MINUTES OF 326th MEETING OF REGISTRATION BOARD

HELD ON 14th to 16th March, 2023

Drug Regulatory Authority of Pakistan

T.F. Complex, Mauve Area, G-9/4

Islamabad.

326th meeting of Registration Board was held on 14th to 16th March, 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.

The Board under Rule 24 (6) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 of the Drugs Act, 1976 decided to co-opt Mr. Iftikhar A. Chaudhary as member of the registration board on excellent performance during his tenure.

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 (Online).	Co-opted Member
3.	Maj. Gen. (R) Dr. Tahir Mukhtar Sayed. Former Inspector General (Hospitals), Fauji Foundation, Rawalpindi.	Co-opted Member
4.	Mr. Iftikhar A. Chaudhary, Ex-Hospital Pharmacist, Lahore	Co-opted Member
5.	Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratories, Islamabad	Co-opted Member
6.	Mr. Ali Ahmad Agha, Director. DTL Quetta Baluchistan	Member
7.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o NFS&R	Co-opted Member
8.	Dr. Ayesha Yaqoob, Rep. of Director DTL Govt. of Punjab Rawalpindi	Member
9.	Mr. Muhammad Aslam, Additional Draftsman-I, Ministry of law & Justice, Islamabad.	Member
10.	Dr. Sartaj Khan, Drug Analyst. Rep. of Director, DTL, Peshawar	Member
11.	Mr. Ajmal Sohail Asif, Director, QA&LT Division	Member
12.	Mr. M. Ahsan Hafiz, Deputy Director, Rep of Division of BE&R	Member
13.	Ms. Sadaf Ahmad, Assistant Director, Rep. of Division of MD&MC	Member

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

Item No. I: Confirmation of Minutes of 325th meetings of Registration Board.

325th meeting of Registration Board was held on 1st March, 2023. Accordingly, draft minutes of 325th meeting of Registration Board were circulated among the members on same day for perusal/approval/comments (if any) by 1500 Hrs. General Tahir Mukhtar thorough email *"Recommended Approval please"*. Ms. Ayesha Ifran through email responded as *"The minutes are recommended for approval please".* Rest of the members did not pass any comment. Hence minutes of 325th meeting of RB stand approved.

Accordingly, fair minutes of 325th meeting of RB were processed for perusal/approval of Chairman, Registration Board. After approval from Chairman Registration Board, fair minutes of 325th meeting of Registration Board were circulated among relevant Divisions / Sections for implementation / compliance of decisions.

Decision: Registration Board noted the information and unanimously confirmed the minutes of 325th meeting of Registration Board.

Item No. II 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.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
14.	Mr. Zia Ullah	Ex AD PEC
15.	Mr. Ishtiaq	Ex AD PEC

Case No. 01 Registration applications on Form 5F (Human)
a) New cases:

1.	Name, address of Applicant / Marketing Authorization Holder	**M/s Med Asia Pharmaceutical (Pvt) Ltd. Plot No. 7, Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 1891 dated 20-01-2022
	Details of fee submitted	Rs.75,000/- dated 04-01-2022
	The proposed proprietary name / brand name	**Synec 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 500mg powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Droncef injection 500mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. 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. 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 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 innovator i.e. Rocephin Injection 500mg. The results of all the tests of both products falls within the specifications and are comparable. The firm has also performed compatibility studies of the product with recommended diluent i.e. sterile water for injection. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.		
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.		
	STABILITY STUDY DATA			
	Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.		
	API Lot No.	Q011812004		
	Description of Pack (Container closure system)	Vials containing powder for reconstitution, packed in unit carton		
	Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
	Time Period	Real time: 6 months Accelerated: 6 months		
	Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
	Batch No.	001	002	003
	Batch Size	8389 vials	8389 vials	8389 vials
	Manufacturing Date	01-2019	01-2019	02-2019
	Date of Initiation	12-02-2019	14-02-2019	10-03-2019
	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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
	2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
	3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 100Kg ceftriaxone sodium dated 08-01-2019. The invoice is signed by AD (I&E) DRAP Islamabad office.
	4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability 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:

- The applied product to be manufactured by M/s Seraph Pharmaceuticals 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 Amson Vaccines and Pharma Pvt Ltd. Plot No. 154, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	CESOD Injection 500mg IV
Batch No. of drug product	001, 002, 003
Case No.	784
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.**

2.	Name, address of Applicant / Marketing Authorization Holder	**M/s Med Asia Pharmaceutical (Pvt) Ltd. Plot No. 7, Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial

		Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 1890 dated 20-01-2022
	Details of fee submitted	Rs.75,000/- dated 04-01-2022
	The proposed proprietary name / brand name	**Synec 1g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1g
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 1g powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Droncef injection 1g by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. 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. 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 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 innovator i.e. Rocephin Injection 1g. The results of all the tests of both products falls within the specifications and are comparable. The firm has also performed compatibility studies of the product with recommended diluent i.e. sterile water for injection. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.		
API Lot No.	Q011812004		
Description of Pack (Container closure system)	Vials containing powder for reconstitution, packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	8389 vials	8389 vials	8389 vials
Manufacturing Date	01-2019	01-2019	02-2019
Date of Initiation	12-02-2019	14-02-2019	10-03-2019
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board.

			• Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
	2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
	3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 100Kg ceftriaxone sodium dated 08-01-2019. The invoice is signed by AD (I&E) DRAP Islamabad office.
	4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability 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:

- The applied product to be manufactured by M/s Seraph Pharmaceuticals 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 Amson Vaccines and Pharma Pvt Ltd. Plot No. 154, Industrial Triangle Kahuta Road Islamabad.
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	CESOD Injection 1g IV
Batch No. of drug product	001, 002, 003
Case No.	785
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.**

3.	Name, address of Applicant / Marketing Authorization Holder	**M/s Med Asia Pharmaceutical (Pvt) Ltd. Plot No. 7, Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

		(Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 8293: 30-03-2022
	Details of fee submitted	PKR 75,000/-: 07-03-2022
	The proposed proprietary name / brand name	**Synec 250mg IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 250mg powder for solution for injection (MHRA Approved)
	For generic drugs (me-too status)	Droncef injection 250mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. 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. 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 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 innovator i.e. Rocephin Injection 250mg. The results of all the tests of both products falls within the specifications and are comparable. The firm has also performed compatibility studies of the product with recommended diluent i.e. sterile water for injection. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.		
API Lot No.	Q011812004		
Description of Pack (Container closure system)	Vials containing powder for reconstitution, packed in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	8389 vials	8389 vials	8389 vials
Manufacturing Date	01-2019	01-2019	02-2019
Date of Initiation	12-02-2019	14-02-2019	10-03-2019
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP

		and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 100Kg ceftriaxone sodium dated 08-01-2019. The invoice is signed by AD (I&E) DRAP Islamabad office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability 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:

- The applied product to be manufactured by M/s Seraph Pharmaceuticals Islamabad have already been approved by Registration Board in its 307th 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 307th meeting are as follows:

Applicant firm	M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat Lahore.
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	SNARE Injection 250mg IV
Batch No. of drug product	001, 002, 003
Case No.	28
RB meeting	307

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.**

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Med Asia Pharmaceutical (Pvt) Ltd. Plot No. 7, Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 1887 dated 20-01-2022
	Details of fee submitted	Rs. 75,000/-: 07-03-2022
	The proposed proprietary name / brand name	**Unixime 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	Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	30ml bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 100mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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.
	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 and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Dry powder for suspension 100mg/5ml". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The

		analysis of all quality tests were performed according to USP monograph. The results depicts that the developed formulation is comparable to the comparator product. The firm has also performed compatibility studies of the product with diluent i.e. purified (boiled and cooled water). Firm has performed testing of assay pH and other parameters for 7 days at room temperature and 14 days at 2 – 8 ºC and the results after reconstitution were within the acceptable range specified by the firm.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	17CF10172		
Description of Pack (Container closure system)	1's bottle of powder for suspension packed in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	10,000 bottles	10,000 bottles	10,000 bottles
Manufacturing Date	01-2018	01-2018	03-2018
Date of Initiation	18-01-2018	19-01-2018	26-03-2018
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Saakh Pharma is submitted by the firm. Copy of GMP certificate of M/s Saakh Pharma dated 15-01-2018 issued on the basis of inspection dated 16-10-2017 is submitted by the firm. The certificate is issued by Additional Director DRAP Karachi.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 12-01-2018 specifying purchase of 50Kg cefixime from Saakh Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- The applied product to be manufactured by M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad have already been approved by Registration Board in its 297th 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 297th meeting are as follows:

Applicant firm	M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Saf-Xime 100mg/5ml Dry suspension
Batch No. of drug product	001, 002, 003
Case No.	279
BR Meeting	297

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.**

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Med Asia Pharmaceutical (Pvt) Ltd. Plot No. 7, Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 1888 dated 20-01-2022
	Details of fee submitted	Rs.75,000/- dated 04-01-2022
	The proposed proprietary name / brand name	**Unixime 200mg/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	Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	30ml bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 200mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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.
	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 and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Dry powder for suspension 200mg/5ml". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to USP monograph. The results depicts that the

		developed formulation is comparable to the comparator product. The firm has also performed compatibility studies of the product with diluent i.e. purified (boiled and cooled water). Firm has performed testing of assay pH and other parameters for 7 days at room temperature and 14 days at 2 – 8 °C and the results after reconstitution were within the acceptable range specified by the firm.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA			
Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	17CF10172		
Description of Pack (Container closure system)	1's bottle of powder for suspension packed in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	10,000 bottles	10,000 bottles	10,000 bottles
Manufacturing Date	01-2018	01-2018	03-2018
Date of Initiation	18-01-2018	19-01-2018	26-03-2018
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Saakh Pharma is submitted by the firm. Copy of GMP certificate of M/s Saakh Pharma dated 15-01-2018 issued on the basis of inspection dated 16-10-2017 is submitted by the firm. The certificate is issued by Additional Director DRAP Karachi.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 12-01-2018 specifying purchase of 50Kg cefixime from Saakh Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- The applied product to be manufactured by M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad have already been approved by Registration Board in its 297th 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 297th meeting are as follows:

Applicant firm	M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Saf-Xime 200mg/5ml Dry suspension
Batch No. of drug product	001, 002, 003
Case No.	280
BR Meeting	297

Decision: Approved.

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

6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Med Asia Pharmaceutical (Pvt) Ltd. Plot No. 7, Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 2627 dated 27-01-2022
	Details of fee submitted	Rs.75,000/- dated 04-01-2022
	The proposed proprietary name / brand name	**Unixime 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Capsule contained in Alu Alu blister
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 400mg capsule by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. 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.
	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 and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Capsule 400mg". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to JP monograph. Firm has also performed comparative dissolution profile

		(CDP) testing in three dissolution mediums concluding acceptable values for f2 factor.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	17CF10172		
Description of Pack (Container closure system)	1 x 5's capsule in alu-alu blister packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	55,500 capsule	55,500 capsule	55,500 capsule
Manufacturing Date	01-2018	03-2018	05-2018
Date of Initiation	19-01-2018	16-03-2018	10-05-2018
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Saakh Pharma is submitted by the firm. Copy of GMP certificate of M/s Saakh Pharma dated 15-01-2018 issued on the basis of inspection dated 16-10-2017 is submitted by the firm. The certificate is issued by Additional Director DRAP Karachi.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 12-01-2018 specifying purchase of 50Kg cefixime from Saakh Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we

		have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- After the notification of monograph of Cefixime capsule by Registration Board, the manufacturer firm i.e. Seraph Pharmaceuticals has submitted product testing report of their batches which are tested as per the monograph approved vide No. F.14-1/2022-PEC dated 14th March 2022.
- The applied product to be manufactured by M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad have already been approved by Registration Board in its 297th 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 297th meeting are as follows:

Applicant firm	M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.
Manufacturer firm	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	Saf-Xime 400mg Capsule
Batch No. of drug product	001, 002, 003
Case No.	278
BR Meeting	297

Decision: Approved with manufacturer specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022. 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.

7.	Name, address of Applicant / Marketing Authorization Holder	M/s Mass Pharma Pvt. Ltd. Lahore 17-Km Ferozpur Road, Lahore.
	Name, address of Manufacturing site.	M/s Mass Pharma Pvt. Ltd. Lahore 17-Km Ferozpur Road, Lahore.
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy.No 23132 dated 08-11-2019
	Details of fee submitted	Rs.20,000 dated 08-11-2019
	The proposed proprietary name / brand name	**Aqua Pro 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains; Sterilized water for Injection …….. 10 ml
	Pharmaceutical form of applied drug	Ampoule
	Pharmacotherapeutic Group of (API)	Diluent for Injections
	Reference to Finished product specifications	BP
	Proposed Pack size	1's , 10's 50's and 100's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Water for Injection (HOSPIRA) USFDA Approved

	For generic drugs (me-too status)	Water for Injection by M/s. Healthtek Karachi; Reg. No. 076482
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Name and address of API manufacturer.	Bulk water for Injection is manufactured In-House.
	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 Bulk WFI is present in BP. The firm as submitted detail of nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, tests for impurity , 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	N/A. Bulk WFI is always prepared freshly before use.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Water for Injection by Bosch Pharmaceuticals by performing quality tests (Apperance, Conductivity, TOC, Nitrates, Sulfates, Calcium& Magnesium, Sterility testing and BET).
	Analytical method validation/verification of product	N/A.

STABILITY STUDY DATA

Manufacturer of API	M/s Mass Pharma Pvt. Ltd. Lahore 17-Km Ferozpur Road, Lahore		
API Lot No.	8502-7090, 1065-7691, 1066-7692		
Description of Pack (Container closure system)	Transparent glass ampoule (Type-1).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 7690 (18 months) 7691&7692 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 and 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 (Months)		
Batch No.	7090	7691	7692
Batch Size	10,800 Ampoules	5200 Ampoules	5200 Ampoules
Manufacturing Date	09-2020	06-2021	06-2021

Date of Initiation	05-10-2020	10-07-2021	10-07-20251
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.	N/A
3.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A
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:

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 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 24084 dated 01-09-2021
	Details of fee submitted	Rs.30,000/- dated 21-06-2021
	The proposed proprietary name / brand name	**Trox 5 mg / 5 mL oral solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL contains: Cetirizine Dihydrochloride .... 5 mg
	Pharmaceutical form of applied drug	Clear & transparent, sweet with characteric flavor oral solu filled in 60 mL amber glass bottle sealed with pilfer proof aluminium caps
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	BP
	Proposed Pack size	1 ×60 mL

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zirtek Allergy Solution 1 mg/ml oral solution by M/s UCB Pharma, MHRA Approved.
	For generic drugs (me-too status)	Avec 5 mg/ 5 mL oral solution by M/s Platinum Pharma, Reg. No. 025507
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Oral Liquid Syrup section approved.
	Name and address of API manufacturer.	Supriya Life science Ltd., Mumbai, INDIA. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cetirizine Dihydrochloride is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(SLL/CTR/0309047, SLL/CTR/0309048, SLL/CTR/0309047)
	Module-III (Drug Product):	The firm has submitted 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 ***Zyrtec oral solution*** by GSK Pharma by performing quality tests (Identification, Assay, pH, Uniformity of dosage form & related substances). CDP – Not applicable
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Supriya Life science Ltd., Mumbai, INDIA. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.
API Lot No.	CTZ/083/20-21
Description of Pack (Container closure system)	Clear & transparent, sweet with characteric flavor oral solution filled in 60 mL amber glass bottle sealed with pilfer proof aluminium caps
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-97	T-98	T-99
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	19-10-2020	19-10-2020	19-10-2020
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 GMP certificate No. NEW-WHO-GMP/CERT/KD/103995/2021/11/38094 issued by Food and Drug Administration Maharashtra, India valid till 23-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 wherein the permission to import different APIs Cetirizine dihydrochloride for the purpose of test/analysis and stability studies is granted. Import invoice is attached specifying import of Cetirizine dihydrochloride (batch # CTZ/083/20-21) along with DHL airway bill (4320168341).
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:

Decision: Approved.

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

9.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Karsons Pharmaceuticals, Plot No. 01, Street No. SS-3, National Industrial Zone, Rawat, Rawalpindi.
	Status of the applicant	☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2366 dated 25-01-2022

	Details of fee submitted	Rs.75,000/- dated 29-12-2021
	The proposed proprietary name / brand name	**Winzith 200mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Azithromycin as Dihydrate …….. 200mg
	Pharmaceutical form of applied drug	White to Off White Orange flavored powder for Reconstitution.
	Pharmacotherapeutic Group of (API)	Azithromycin is in a class of medications called macrolide antibiotics.
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	5ml, 10ml, 15ml, 20ml, 22.5ml and 25ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zithromax 200 mg in 5 ml suspension by M/s Pfizer Limited, MHRA Approved.
	For generic drugs (me-too status)	Azo Suspension by M/s, Ethical Laboratories (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	GMP inspection conducted. Dry Powder suspension (General) section approved on 17-Jan-2019
	Name and address of API manufacturer.	M/s Hebei Dongfeng Pharmacetical Co., Ltd. Address: No. 365 Guangyuanxi Str., Yongnian District, HanDan City, Hebei Province.
	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 Azithromycin 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
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the reference product that is Azomax 200mg/5ml manufactured by Novartis Pharma by performing quality tests (Identification, Assay, and pH).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Hebei Dongfeng Pharmacetical Co., Ltd. Address: No. 365 Guangyuanxi Str., Yongnian District, HanDan City, Hebei Province.		
API Lot No.	A20191060		
Description of Pack (Container closure system)	Amber glass bottle packed in unit carton (5ml, 10ml, 15ml, 20ml, 22.5ml and 25ml)		
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.	DS-26	DS-27	DS-32
Batch Size	12500	12500	12500
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	03-01-2020	03-01-2020	03-01-2020
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 GMP certificate# HE20190003 issued by Hebei Drug Administration valid till 13/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice no. SE19N02056-INV in name of M/s Karsons pharmaceuticals, for import of 50Kg Azithromycin, attested by AD DRAP I&E Karachi has been 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:

Section#	Observations	Firm's response
3.2.S.4.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted.

	3.2.P.2.2.1	• CDP studies against the innovator drug product shall be submitted. • Dissolution test has not been performed in the Pharmaceutical equivalence studies.	Firm has submitted CDP studies against the Azomax suspension along with Pharmaceutical equivalence studies including dissolution test.
	3.2.P.5	• A copy of the drug product specification(s) including tests, acceptance criteria and reference to analytical procedure shall be provided from M/s Karsons, instead of presenting the extract of USP monograph. • Evidence of availability of HPLC equipped with auto sampler to maintain 10°C temperature shall be submitted.	Firm has submitted drug product analytical procedure from M/s Karsons Pharma along with analytical method verification studies.
	3.2.P.8.3	• Submit complete raw data sheets for the performance of Assay & Dissolution test during stability studies. • In-use stability studies shall be submitted for reconstituted suspension.	• Submitted. • Firm has submitted 14 days in –use stability studies for the re constituted suspension.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Karsons Pharmaceuticals, Plot No. 01, Street No. SS-3, National Industrial Zone, Rawat, Rawalpindi.**

a. Deferred cases

10.	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 27960 dated 11-10-2021
	Details of fee submitted	PKR 30,000/- Dated: 16/09/2021
	The proposed proprietary name / brand name	**Neurone 3ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 3ml ampoule contains: Vitamin B1 (Thiamine HCl) USP…….100mg Vitamin B6 (Pyridoxine HCl) USP…….100mg Vitamin B12(Cyanocobalamin)USP….1000mcg

	Pharmaceutical form of applied drug	Red color clear solution filled in amber glass ampoules with white color breaking ring
	Pharmacotherapeutic Group of (API)	Vitamin B compound
	Reference to Finished product specifications	Innovator
	Proposed Pack size	3ml×25's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Neurobion solution for injection by M/s Merck Selbstmedikation GmbH. Germany Approved
	For generic drugs (me-too status)	Neurobion injection by M/s Martin Dow Marker Ltd. Reg. No. 001485
	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.	Thiamine HCl & Pyridoxine HCl: M/s Jiangxi Tianxin Pharmaceuticals Co., Ltd Cyanocobalamin: M/s Hebei North China Pharmaceutical Huahang Pharmaceutical Co., Ltd.
	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 Pyridoxine Hydrochloride, Thiamine Hydrochloride and Cyanocobalamin is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related compounds by HPLC and impurities by Residue on Ignition, 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	**Thiamine Hydrochloride:** 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:(TH130130130, TH130130131, TH130130132) **Pyridoxine Hydrochloride:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches:(PH2084024, PH2084025, PH2084026) **Cyanocobalamin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Batches:(000707, 011013, 020716) Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches:(C190601C, C190602C, C190603C)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its

		validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Neurobion injection by Martin Dow Marker 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	**Thiamine HCl & Pyridoxine HCl:** M/s Jiangxi Tianxin Pharmaceuticals Co., Ltd **Cyanocobalamin:** M/s Hebei North China Pharmaceutical Huahang Pharmaceutical Co., Ltd.		
API Lot No.	**Thiamine Hydrochloride:** TH20115047 **Pyridoxine Hydrochloride:**PH18114018 **Cyanocobalamin:** C201101		
Description of Pack (Container closure system)	USP Type-I amber Glass ampoules in PVC Tray, packed in unit carton (3ml×25'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.	21ARn051	21ARn052	21ARn053
Batch Size	1500 ampoules	1500 ampoules	1500 ampoules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	21-05-2021	21-05-2021	21-05-2021
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.	**Pyridoxine HCl and Thiamine HCl**: Copy of GMP certificate No. JX20170016 issued by PRC valid till 07/05/2022 **Cyanocobalamin:** Copy of GMP certificate No. HE20 190092M issued by PRC valid till 01/09/2024
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 Pyridoxine HCl, Thiamine HCl and Cyanocobalamin for the purpose of test/analysis and stability studies is granted. • DHL No.XMLPI 6.2/90-1604 dated 19/11/2020 & DHL No. V4955EL4OKM Dated: 18-12-2020
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[II]:

Section#	Observations	Firm's response
3.2.P.1	• Submit the justification for including anti-microbial preservative in applied formulation. • Justify the quantities of each API mentioned in composition table against the label claim.	• Benzyl alcohol is also used as solvent to enhance the solubility of ingredients and it is used as solvent in our formulation. Mistakenly only one function (antimicrobial preservative) was written under section 3.2.P.1. • Quantities of each API is written per 3.15ml to achieve the volume NLT 3ml per unit. Quantities of API are corrected to per 3ml.
3.2.P.3.2	• Justify the quantities of each API mentioned in composition table against the label claim. • Submit the batch formulation for commercial batch size.	• Quantities of each API is written per 3.15ml to achieve the volume NLT 3ml per unit. Quantities of API are corrected to per 3ml. • Batch formulation for commercial batch size is submitted
3.2.P.3.3	Justification shall be submitted for applying UV spectrophotometric method for the analysis of Cyanocobalamin in the finished product.	As applied product is not available in official monographs and USP method of analysis for Cyanocobalamin API and injection is also by UV method, so in-house UV method was developed and validated for analysis of cyanocobalamin.
3.2. P.5.3	• Justify the performance of specificity parameter for cyanocobalamin, without analyzing the sample solution containing Pyridoxine HCl & Thiamine. • Justify the performance of specificity parameter for Pyridoxine HCl & Thiamine without analyzing the sample solution of injection.	Specificity parameter for cyanocobalamin was performed by preparing a placebo solution including Pyridoxine HCl & Thyamine HCl along with excipients. Specificity parameter for Pyridoxine HCl & Thyamine HCl was performed by preparing a placebo solution including cyanocobalamin along with excipients.
3.2. P.8	• Submit stability studies data till 6th month time point for both accelerated and long-term stability conditions. • Submitted stability studies data does not include test for "Antimicrobial effectiveness", as recommended by USP general chapter <51>. Justify this disparity since proposed formulation contains "benzyl alcohol" as an antimicrobial agent. •Justify the performance of terminal sterilization by autoclave method for the vitamin containing formulation.	6th month stability data has been submitted. Benzyl alcohol is used as solvent in applied product formulation, additionally the said test is recommended for multi dose sterile products while applied product is single dose solution for injection and not stored after opening so test was not performed. • The applied product was sterilized by filtration method and test of finish product and stability studies are concluded on product sterilized by filtration method, some portion was autoclaved to check the effect of autoclavation on pH and color of product. • Firm has submitted machine usage log book of terminal sterilizer wherein sample portion has been recorded as 25 ampoules for the batches of applied product. • Revised BMR for commercial manufacturing has been submitted.

Decision: Deferred for the scientific justification of the claimed role of Benzyl alcohol as solvent and not as preservative in the applied formulation.

Firm Response:

- In applied product benzyl alcohol was used to support the solubility of active ingredients (Pyridoxine Hydrochloride, Thiamine Hydrochloride and Cyanocobalamin) which are already soluble in water, so no need to use any additional solvent/solubilizing agent i-e benzyl alcohol.
- Applied product is single dose sterile solution for injection so use of preservative is also not required.
- As benzyl alcohol is not part of innovator formulation and as mentioned above do not have any significant role in applied product formulation so **we hereby undertake we will not use benzyl alcohol in our commercial batches formulation.**

Discussion: Registration Board deliberated that the firm has used benzyl alcohol as an excipient which is not used by the innovator drug product. The drug product is a single use sterile injection containing water soluble drug substances therefore the use of benzyl alcohol is not justified.

Decision of 317th meeting: Registration Board deferred the case for following:

- Submission of 3 months stability studies data with frequency of 0,1& 3 months, at both accelerated and long-term conditions, for three new batches, manufactured with revised formulation excluding benzyl alcohol.
- Full fee of registration i.e., Rs. 30,000 for for submission of new stability studies data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Response by Firm: Firm has submitted following:

- Batch manufacturing record of three newly manufactured stability batches wherein Benzyl alcohol is not included in the formulation.
- Stability studies of three newly manufactured batches detailed hereafter, at both accelerated and long term conditions with testing frequency of 0,1& 3 months.
- Fee of Rs. 30,000/- vide deposit slip# 65483381838.

Batch No.	22ARn004	22ARn005	22ARn006
Batch Size	1200 ampoules	1200 ampoules	1200 ampoules
Manufacturing Date	07-2022	07-2022	07-2022

Decision of 326th meeting: Approved.

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

Registration Board further advised to send a reference to QA & LT Division for verification of the submitted data of applied formulation during any upcoming inspection of the firm.

11.	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 25696 dated 15-09-2021
	Details of fee submitted	PKR 30,000/- Dated: 31/08/2021
	The proposed proprietary name / brand name	**Troket 30mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Ketorolac Tromethamine USP…….30mg

	Pharmaceutical form of applied drug	Clear and colorless solution filled in clear glass ampoules with red and blue ACF rings and blue color OPC mark
	Pharmacotherapeutic Group of (API)	Anti-inflammatory, non-steroid
	Reference to Finished product specifications	USP
	Proposed Pack size	1ml×5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ketorolac Tromethamine injection 30mg/ml by M/s Peckforton Pharmaceuticals Limited Crewe Hall, Crewe, Cheshire, CW1 6UL, United Kingdom, MHRA Approved.
	For generic drugs (me-too status)	Toradol Injection 30mg/ml by M/s Barrett Hodgson Pakistan (Pvt.) Ltd. Reg. No. 015000
	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.	M/s PERKIN LABORATORIES, plot No. 94 TSIIC, Industrial estate, Medchal Dist. 501401, Telangana, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ketorolac Tromethamine 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 organic impurities by HPLC (impurity A, impurity B, Impurity C and Impurity D), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches:(KM-1102215, KM-1102315, KM-1102415)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Toradol 30mg/ml injection by Sami Pharmaceuticals 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 verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s PERKIN LABORATORIES, plot No. 94 TSIIC, Industrial estate, Medchal Dist. 501401, Telangana, INDIA	

API Lot No.	KM-1104620		
Description of Pack (Container closure system)	USP Type-I Glass ampoules in PVC Tray, packed in unit carton (1ml×5's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21ARn033	21ARn034	21ARn035
Batch Size	2500 ampoules	2500 ampoules	2500 ampoules
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	11-05-2021	11-05-2021	11-05-2021
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. 3879/Stores/2019 issued by DCA valid till 10/01/2021.
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 Ketorolac Tromethamine for the purpose of test/analysis and stability studies is granted. • AirWay Bill No. 176-26046624 Dated: 21/12/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator(II):

Section#	Observations	Firm's response
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	Copy of GMP certificate No. 77981/TS/2022 issued by DCA Telangana valid till 02/01/2023 has been submitted.
3.2. S.4.1	Limits for the test of pH are different between the drug substance manufacturer & drug product manufacturer.	As per USP monograph of Ketorolac Tromethamine, Limit for pH is 5.7 – 6.7 which is mentioned in test method and specifications submitted by Drug product manufacturer. Drug substance manufacturer mentioned the pH limit 5.7-6.0 in his specification, however in CoA of drug substance and stability study data submitted by Drug substance manufacturer the limit for pH is mentioned 5.7 – 6.7 (as per USP), copy of CoA provided by Drug substance manufacturer for ketorolac

		Tromethamine having pH limit as per USP (5.7 – 6.7) is submitted
3.2. S.4.2	Sample and standard solution concentration mentioned in the Assay test method from drug substance manufacturer are different from that recommended by USP monograph of "Ketorolac tromethamine".	USP monograph of Ketorolac Tromethamine recommends concentration of reference and sample solution to be 0.4mg/ml for assay test. For Assay test Drug substance manufacturer referred to related substances sample and standard preparation which is 20mg sample dissolved in 50ml of solvent. The resultant concentration becomes 0.4mg/ml which is same as recommended by USP.
3.2.S.7	Long term stability conditions mentioned in summary & conclusion are different from that declared in the stability data submitted in section 3.2.S.7.3.	Long term stability conditions mentioned in summary and conclusion are different from declared in stability data because in DMF the manufacturer mentioned Zone II conditions and provided stability data for long term stability studies at 25ºC/60%RH. After receiving DMF we asked the drug substance manufacturer to provide Zone-IVA (30ºC/65%RH) stability data which is submitted under stability data in section 3.2.S.7.3.
3.2.P.1	• Justify the role of Ethyl alcohol as antimicrobial preservative in the applied formulation. • Reference for use of Citric acid as anti-oxidant in the innovator formulation shall be submitted.	Ethyl alcohol is also used as solvent and penetration enhancer to enhance the solubility of ingredients and it is used as solvent/solubility enhancer in our formulation. By mistake only one function of ethyl alcohol (antimicrobial preservative) was written under section **3.2.P.1** which is corrected and submitted.
3.2.P.2.2.1	Complete testing has not been performed during Pharmaceutical equivalence studies.	Complete testing was performed during Pharmaceutical equivalence studies (mentioned in finish product reports under batch analysis), sterility and endotoxin test were not reported in pharmaceutical equivalence report which is corrected and revised report containing all test and results are submitted.
3.2.P.3.2	Justify the proposed quantity of drug substance in mg/ml against the label claim.	The quantity of drug substance is written mg per 1.1ml to achieve the deliverable volume (NLT 1ml) per unit in section 3.2.P.3.2. However, to clear the ambiguity, quantity of drug substance is corrected to mg/1ml and submitted
3.2.P.3.3	Justify the performance of terminal sterilization by autoclave while ethyl alcohol is used in the formulation	Firm has referred to a patent wherein terminal sterilization has been performed for Ketorolac injection containing Ethyl alcohol.
2.3.R.1.1	• Justify the performance of terminal sterilization by autoclave while ethyl alcohol is used in the formulation. • Submit the minimum handling capacity of the mixing vessel used for the production of trial batches.	• Firm has referred to a patent wherein terminal sterilization has been performed for Ketorolac injection containing Ethyl alcohol. • Minimum handling capacity of mixing vessel used in production of trial batches is 1.5 liters.

Decision: Deferred for scientific rationale of performing terminal sterilization, with reference to the innovator product.

Firm Response: After extensive search at product development stage we did not found any innovator document either recommending terminal sterilization or prohibiting from it, so we chose a safe combination of sterilization procedure for applied product i-e **Terminal sterilization along with filtration**.

We performed sterilization of applied product by filtration before filling and sealing (mentioned in BMR provided in CTD) and then terminally sterilized it.

After manufacturing and sterilization of applied product by above mentioned procedure we performed finish product analysis and stability studies **(accelerated and long term)** for six months on filtered and terminally sterilized drug product and the results were satisfactory **(results provided in CTD under Batch analysis and Stability Studies).**

Discussion: Registration Board deliberated that the innovator product has not recommended terminal sterilization for the applied product and that it is also not recommended when volatile solvents like ethyl alcohol is used in the formulation.

Decision of 317th meeting: Registration Board deferred the case for following:

- Submission of 3 months stability studies data with frequency of 0,1& 3 months, at both accelerated and long-term conditions, for three new batches, manufactured without terminal sterilization.

- Full fee of registration i.e., Rs. 30,000 for for submission of new stability studies data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Response by Firm: Firm has submitted following:

- Batch manufacturing record of three newly manufactured stability batches wherein terminal sterilisation has not been included in the manufacturing method.
- Stability studies of three newly manufactured batches detailed hereafter, at both accelerated and long term conditions with testing frequency of 0,1& 3 months.
- Fee of Rs. 30,000/- vide deposit slip# 92930916838.

Batch No.	22ARn001	22ARn002	22ARn003
Batch Size	1800 ampoules	1800 ampoules	1800 ampoules
Manufacturing Date	07-2022	07-2022	07-2022

Decision of 326th meeting: Approved.

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

Registration Board further advised to send a reference to QA & LT Division for verification of the sterilization procedure during any upcoming inspection of the firm.

12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals 7KM Pasrur Road Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F.1-19/2014-Lic. from Secretary CLB for issuance of DML, declaring availability of "tablet general section".
	Dy. No. and date of submission	Dy.No 23835 dated 31-08-2021
	Details of fee submitted	Rs.20,000/- dated 22-04-2021
	The proposed proprietary name / brand name	**Caltis 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet Contains: Clarithromycin ……. 250mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 250mg tablet, Teva Pharmaceutical, MHRA Approved.
	For generic drugs (me-too status)	Rithmo 250mg tablet, Sami Pharmaceuticals (Pvt.) Limited.

	GMP status of the Finished product manufacturer	New DML was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 29-08-2018, including Capsule general section
	Name and address of API manufacturer.	Zhejiang Better Pharmaceuticals Co., Ltd. Sanjiang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Klacid 250mg tablet by Abbvie S.r.l Italy by performing quality tests. CDP has been performed against the Klacid 250mg tablet by Aesica Queenborough UK in Acid media (pH 1.0-1.2) & Acetate buffer 4.5pH 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Better Pharmaceuticals Co., Ltd. Sanjiang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang, P.R. China.		
API Lot No.	A022006051		
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.	20TRn019	21TRn001	21TRn002
Batch Size	2000 tab	1000 tab	1000 tab
Manufacturing Date	12-2020	01-2021	01-2021

Date of Initiation	06-01-2021	12-01-2021	12-01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. (New Section)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.12086/2020/DRAP-AD-G (I&E) dated 28/08/2020 is submitted wherein the permission to import different APIs including Clarithromycin for the purpose of test/analysis and stability studies is granted. • **DHL No.** 2020-11-16 XMLPI 6.2/90-1604 WAYBILL 41 0121 2102
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	--
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.1	Differential fee of Rs. 10,000/- shall be submitted as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Differential fee of Rs. 10,000/- has been paid vide deposit slip# 9995357177 dated 20-06-2022
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	Firm has submitted a document for " Written confirmation for active substances exported to EU' instead of GMP certificate, Zheijiang Food & Drug Administration.
3.2.S.4.2	Submit drug substance analytical record performed by M/s Islam pharma.	Submitted
3.2.P.2.2.1	In Pharmaceutical equivalence studies dissolution test has not been performed as per the USP monograph of Clarithromycin tablets.	Firm has submitted Dissolution test performance in continuation to Pharmaceutical equivalence studies.
3.2.P.3.2	• Justify the proposed quantity of Clarithromycin of 257.334mg per tablet in the batch formula against the label claim of 250mg per tablet. • A batch formula for proposed commercial batch size shall be provided	• Firmhas justified proposed quantity against the actual potency of drug substance determined on as is basis. • Commerical batch formula is submitted.
3.2.P.3.5	Submitted process validation protocol does not include sampling plan.	Revised process valiation protocol has been submitted.
3.2.P.8.3	➢ Submitted chromatograms of initial time point analysis declares file created date i.e., 18-02-2021 which is subsequent to the acquired date mentioned on each chromatogram. Clarification shall be submitted in this regard. ➢ Justification shall be submitted for calculating dissolution results based upon one value for standard peak area. ➢ Following shall be submitted:	• Laptop attached to the HPLC stopped working due to some fault and its hard disc was corrupted in Feb-2021 due to which new laptop was installed with HPLC. Previous data was recovered and transferred on 18-02-2021 to new laptop.

		➢ 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). Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	• A new set of chromatograms print out for DRAP submission was taken after above incident so the chromatograms are showing file created date as 18-02-2021 (which is date if saved data transfer to new laptop) after the acquired date • HPLC system digital log has been submitted excluding for the intial time point analysis. • Record of Digital data logger for temperature and humidity monitoring of stability chamber is submitted. • Firm has submitted copy of commercialinvice which is not attested by DRAP I&E office.

Previous Decision: Deferred for following:

- Submission of valid GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority.
- Onsight verification for the claim of the firm regarding disparity between date of acquisition & date of file creation in the submitted chromatograms.

Firm's response:

Firm has submitted following:

- DML certificate# ZJ20050286 of M/s Zhejiang Better Pharmaceuticals Co., Ltd. Sanjiang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang, P.R. China valid till 09-11-2025, issued by Zheijiang Drug Administration.
- As mentioned in previous reply to the deficiencies letter No. F. 1-1/2019/PEC-DRAP (AD PEC-II) dated: 08th June, 2022 that new set of chromatograms was printed for CTD submission which was taken after the laptop fault and reinstallation of recovered data to new laptop, we also printed the chromatograms on date of test for all analysis and are part of analytical record.
- Copy of chromatograms printed on date of analysis for initial time point analysis for applied product containing same acquisition and file creation date is submitted.

Decision of 326th meeting: Approved.

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

Registration Board further advised to send a reference to QA & LT Division for verification of the submitted data of applied formulation during any upcoming inspection of the firm.

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

	Dy. No. and date of submission	Dy.No 23834 dated 31-08-2021
	Details of fee submitted	Rs.20,000/- dated 22-04-2021
	The proposed proprietary name / brand name	**Caltis 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet Contains: Clarithromycin ……. 500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Clarithromycin 500mg tablet, Teva Pharmaceutical, MHRA Approved.
	For generic drugs (me-too status)	Rithmo 500mg tablet, Sami Pharmaceuticals (Pvt.) Limited.
	GMP status of the Finished product manufacturer	New DML was granted after inspection vide letter No. F. 1-19/2014-Lic (Vol-1) Dated: 29-08-2018, including Capsule general section
	Name and address of API manufacturer.	Zhejiang Better Pharmaceuticals Co., Ltd. Sanjiang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Klacid 500mg tablet by Aesica Queenborough UK by performing quality tests. CDP has been performed against the Klacid 500mg tablet by Aesica Queenborough UK in Acid media (pH 1.0-1.2) & Acetate buffer 4.5pH 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Better Pharmaceuticals Co., Ltd. Sanjiang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang, P.R. China.		
API Lot No.	A022006051		
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.	20TRn018	20TRn024	20TRn025
Batch Size	2000 tab	1000 tab	1000 tab
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)	The firm has not submitted any document. (New Section)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.12086/2020/DRAP-AD-G (I&E) dated 28/08/2020 is submitted wherein the permission to import different APIs including Clarithromycin for the purpose of test/analysis and stability studies is granted. • **DHL No.** 2020-11-16 XMLPI 6.2/90-1604 WAYBILL 41 0121 2102
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	--
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.1	Differential fee of Rs. 10,000/- shall be submitted as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Differential fee of Rs. 10,000/- has been paid vide deposit slip# 94806947378 dated 20-06-2022
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	Firm has submitted a document for " Written confirmation for active substances exported to EU' instead of GMP certificate, Zheijiang Food & Drug Administration.
3.2.S.4.2	Submit drug substance analytical record performed by M/s Islam pharma.	• Submitted

		• Firm has submitted Dissolution test performance in continuation to Pharmaceutical equivalence studies.
3.2.P.2.2.1	• In Pharmaceutical equivalence studies dissolution test has not been performed as per the USP monograph of Clarithromycin tablets. • In Pharmaceutical equivalence studies submitted chromatograms of initial time point analysis declares file created date i.e., 18-02-2021 which is earlier to the acquired date mentioned on each chromatogram.	• Laptop attached to the HPLC stopped working due to some fault and its hard disc was corrupted in Feb-2021 due to which new laptop was installed with HPLC. Previous data was recovered and transferred on 18-02-2021 to new laptop. • A new set of chromatograms print out for DRAP submission was taken after above incident so the chromatograms are showing file created date as 18-02-2021 (which is date if saved data transfer to new laptop) after the acquired date 29-12-2020.
3.2.P.3.2	• Justify the proposed quantity of Clarithromycin of 514.668mg per tablet in the batch formula against the label claim of 500mg per tablet. • A batch formula for proposed commercial batch size shall be provided	• Firm has justified proposed quantity against the actual potency of drug substance determined on as is basis. • Commerical batch formula is submitted.
3.2.P.3.5	Submitted process validation protocol does not include sampling plan.	Revised process valiation protocol has been submitted.
3.2.P.8.3	➢ Submitted chromatograms of initial time point analysis declares file created date i.e., 18-02-2021 which is earlier to the acquired date mentioned on each chromatogram. Clarification shall be submitted in this regard. ➢ Justification shall be submitted for calculating dissolution results based upon one value for standard peak area. ➢ Following shall be submitted: ➢ 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). Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	• Laptop attached to the HPLC stopped working due to some fault and its hard disc was corrupted in Feb-2021 due to which new laptop was installed with HPLC. Previous data was recovered and transferred on 18-02-2021 to new laptop. • A new set of chromatograms print out for DRAP submission was taken after above incident so the chromatograms are showing file created date as 18-02-2021 (which is date if saved data transfer to new laptop) after the acquired date. • All of three batches on stability studies were tested on same day at each time point so only one standard solution for dissolution was injected and calculations were made against same one standard value. • HPLC system digital log has been submitted excluding for the intial time point analysis. • Record of Digital data logger for temperature and humidity monitoring of stability chamber is submitted. • Firm has submitted copy of commercialinvice which is not attested by DRAP I&E office.

Decision of 320th meeting: Deferred for following:

- Submission of valid GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority.
- Onsight verification for the claim of the firm regarding disparity between date of acquisition & date of file creation in the submitted chromatograms.

Firm's response:

Firm's response:

Firm has submitted following:

- DML certificate# ZJ20050286 of M/s Zhejiang Better Pharmaceuticals Co., Ltd. Sanjiang Road, Paojiang Industrial Zone, Shaoxing, Zhejiang, P.R. China valid till 09-11-2025, issued by Zheijiang Drug Administration.
- As mentioned in previous reply to the deficiencies letter No. F. 1-1/2019/PEC-DRAP (AD PEC-II) dated: 08th June, 2022 that new set of chromatograms was printed for CTD submission which was taken after the laptop fault and reinstallation of recovered data to new laptop, we also printed the chromatograms on date of test for all analysis and are part of analytical record.
- Copy of chromatograms printed on date of analysis for initial time point analysis for applied product containing same acquisition and file creation date is submitted.

Decision of 326th meeting: Approved.

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

Registration Board further advised to send a reference to QA & LT Division for verification of the submitted data of applied formulation during any upcoming inspection of the firm.

14.	Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. 44-Indutrial Triangle Kahuta Road Islamabad Pakistan
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. 44-Indutrial Triangle Kahuta Road Islamabad Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 12514 dated 23-05-2022
	Details of fee submitted	Rs.30,000/- dated 20-05-2022
	The proposed proprietary name / brand name	**Ulfam dry Suspension 40mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Famotidine …… 40mg
	Pharmaceutical form of applied drug	Powder for suspension
	Pharmacotherapeutic Group of (API)	Histamine H2 receptor antagonist
	Reference to Finished product specifications	USP Spec's
	Proposed Pack size	60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Pepcid 40mg/5ml Dry Suspension by M/s Salix Pharms USA.
	For generic drugs (me-too status)	Famlet 40mg/5ml Dry Suspension By M/s Winlet Pharmaceuticals Pvt., Ltd. Reg. No. 098322

	GMP status of the Finished product manufacturer	GMP inspection report conducted on 29-12-2020 concluding acceptable level of GMP compliance.
	Name and address of API manufacturer.	M/s Rakshit Pharmaceuticals Limited Plot No.68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Visakhapatnam District, Andhra Pradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Famotidine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (FM/08/00/017, FM/08/00/018, FM/08/00/019)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Famlet Dry Suspension 100mg/5ml by Winlet Pharmaceuticals Pvt., Ltd by performing quality tests. As the dissolution of famotidine for oral suspension is not described in USP, hence dissolution comparison was not performed for the product with innovator/ reference product.
	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 Rakshit Pharmaceuticals Limited Plot No.68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Visakhapatnam District, Andhra Pradesh India.
API Lot No.	FT/21/025
Description of Pack (Container closure system)	60ml amber colored 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.	21GT07	21GT08	21GT09
Batch Size	67 Bottles	67 Bottles	67 Bottles
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	10-08-2021	10-08-2021	10-08-2021
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.	Copy of GMP certificate No. E-1555174/DD/DCA/VSP/2021 issued by DCA Andhra Pradesh valid till 21-11-2022 submitted.
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice No. RLP3721E0145, dated 29-09-2021 Famotidine 50 kg imported from Rakshit Pharmaceuticals Limited, attested by AD I&E DRAP dated 20-10-2021 is submitted.
	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	Not submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers is submitted

Remarks of Evaluator:

Section#	**Observation**
1.6.5	Valid GMP certificate of the drug substance manufacturer shall be submitted.
3.2.S.7	Long term stability studies data of drug substance is not as per Zone IVa conditions.
3.2.P.1	Details of accompanying reconstitution diluent shall be submitted.
3.2.P.2.5	Submit data for test for content of antimicrobial preservative & efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter <51>.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.
3.2.P.5.1	Test for content of antimicrobial preservative & efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter <51>, has not been included in the finished product specifications. You are advised to submit justification in this regard. Justification shall be submitted for not including test of "Content uniformity" & "Microbial Enumeration Tests" in the drug product specifications as recommended by USP monograph. Elaborate the sample preparation method including procedure of reconstitution in the Assay test method.
3.2.P.5.4	Submitted drug product COAs & BMRs declare manufacturing date as of July, 2021, whereas the COA of Famotidine from drug substance manufacture mentions its date of manufacture as August 2021, while date of drug substance analysis in the COA from M/s Focus & Rulz declare date of analysis as 10-08-2021. Justification shall be submitted for the manufacturing of drug product stability batches prior to the date of manufacture of drug substance.
3.2.P.8	Submit justification for not performing tests of content of antimicrobial preservative, efficacy of preservative, "Content uniformity" & "Microbial Enumeration Tests" during stability studies. In-use stability studies of reconstitution diluent have not been submitted.

Decision of 324th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

Section#	Observation	Firm's response
1.6.5	Valid GMP certificate of the drug substance manufacturer shall be submitted.	• Firm has submitted GMP certificate valid till 21-11-2022 issued by Drug Control Administration Andhra Pradesh, India. • Firm has also submitted License Retention certificate declaring that license of firm has been retained for the period from 29-12-2020 to 28-12-2025 issued by Drug Control Administration Andhra Pradesh, India.
3.2.S.7	Long term stability studies data of drug substance is not as per Zone IVa conditions.	Submitted.
3.2.P.1	Details of accompanying reconstitution diluent shall be submitted.	Firm has stated water as the reconstitution diluent.
3.2.P.2.5	Submit data for test for content of antimicrobial preservative & efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter <51>.	Firm has submitted preservative efficacy report for 28 days.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.	Submitted.
3.2.P.5.1	Test for content of antimicrobial preservative & efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter <51>, has not been included in the finished product specifications. You are advised to submit justification in this regard. Justification shall be submitted for not including test of "Content uniformity" & "Microbial Enumeration Tests" in the drug product specifications as recommended by USP monograph. Elaborate the sample preparation method including procedure of reconstitution in the Assay test method.	Firm has submitted revised analytical method and specifications for drug product including test of "Content uniformity" & "Microbial Enumeration Tests".
3.2.P.5.4	Submitted drug product COAs & BMRs declare manufacturing date as of July, 2021, whereas the COA of Famotidine from drug substance manufacture mentions its date of manufacture as August 2021, while date of drug substance analysis in the COA from M/s Focus & Rulz declare date of analysis as 10-08-2021. Justification shall be submitted for the manufacturing of drug product stability batches prior to the date of manufacture of drug substance.	Famotidine (Ulfam 20mg registration No. 011003 and Ulfam 40mg Tablets Registration No. 011004) is our registered products and routine manufactured for market requirements. As evident from BMR submitted with stability studies the material for product development of famotidine dry suspension is used from the lot (QCNO.588RM21) imported for our registered products. GRN, COA, Test report ADC cleared from DRAP office Islamabad dated 20-1 1-2020, Airway bill, Invoice of Drug Substance is attached for your kind consideration We mistakenly enclosed the API data of famotidine of the recent lot that was imported later after the processing of the trial batches of famotidine dry suspension.

			We apologize for the mistake and the correct data of the respective lot used in the product development of famotidine dry is submitted.
	3.2.P.8	Submit justification for not performing tests of content of antimicrobial preservative, efficacy of preservative, "Content uniformity" & "Microbial Enumeration Tests" during stability studies. In-use stability studies of reconstitution suspension have not been submitted.	• Content uniformity of the product is performed during analysis of finished product and data of microbial enumeration test performed during stability studies is compiled separately and enclosed for your kind consideration. • In-use stability studies of reconstitution suspension have not been submitted.

Decision of 326th meeting: Approved.

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

15.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Sachet (General) section approved.
	Dy. No. and date of submission	Dy. No. 24083: Dated: 01-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 21-06-2021
	The proposed proprietary name / brand name	Oestolos 2 g Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Strontium Ranelate……..... 2 g
	Pharmaceutical form of applied drug	Granules in sachet pack
	Pharmacotherapeutic Group of (API)	Anti-osteoporosis
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1 × 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Strontium ranelate Aristo 2 g granules for oral suspension by M/s Aristo Pharma GmbH Wallenroder Straße 8-10 13435 Berlin Germany, MHRA Approved.
	For generic drugs (me-too status)	ONITA SACHET by M/s PHARM-EVO (PVT) LTD, (Reg. No. 057746)
	Name and address of API manufacturer.	M/s Suntril Pharmaceuticals Pvt. Ltd., Plot # 219, Phase-1, HSIIDC, Alipur Tehsil Barwala District Panchkula (Haryana), India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances (unspecified and total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (STRHB 170001, STRHB 170002, STRHB 170003)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Osstium sachet** by **Atco** Pharma by performing quality tests (Identification, Assay, pH, Uniformity of dosage unit & loss on Drying). CDP – Not applicable
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Suntril Pharmaceuticals Pvt. Ltd., Plot # 219, Phase-1, HSIIDC, Alipur Tehsil Barwala District Panchkula (Haryana), India.		
API Lot No.	STRHB200003		
Description of Pack (Container closure system)	Aluminium Foil, 1 × 7's		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-100	T-101	T-102
Batch Size	100 Sachet	100 Sachet	100 Sachet

Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	22-10-2020	22-10-2020	22-10-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. 1/151-2 Drug-1-2019/7839 issued by Food and Drug Administration Haryana Panchkula (India) valid till 22-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No. 17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to import different API Strontium Ranelate for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameter were not provided.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameters were not provided.
4.	The reference formulation states granules for oral suspension for applied formulation. Clarification is required in manufacturing process and process control whether granules will be prepared in-house or otherwise.	Granules are prepared in-house by sieving the materials from appropriate mesh.
5.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	The firm has submitted pharmaceutical equivalence with comparator product Osstium Sachet of M/s Atco Labs.
6.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Oestolos 2g Sachet = T-100 Comparator batch no.: Osstium Sachet = UJ006FM1

7.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications
8.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
9.	Provide raw data sheets wherein details of sample solution preparation and standard solution and calculation formula for the assay test shall be mentioned	The firm has submitted raw data sheets for the assay test.
10.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has not submitted invoice for the procurement of drug substance.
11.	Justification is required for submission of single chromatogram as test result of each batch at different time intervals.	The firm has not submitted chromatograms for real time and accelerated stability studies at different time intervals. Instead, single chromatogram for each test interval is submitted.

Deferred for submission of following:

Sr. No.	**Decision of 316th meeting of RB**	**Response by the firm**
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports of strontium ranelate by performing precision, linearity, accuracy, specificity and system suitability studies.
2.	HPLC chromatograms of all time points of real time and accelerated stability studies.	The firm has submitted HPLC chromatograms of real time and accelerated stability studies for 0, 3 and 6-month time point.
3.	Analytical method verification reports of drug product performed by drug product manufacturer.	Analytical method verification reports of strontium ranelate by performing precision, linearity, accuracy, and specificity have been submitted.
4.	Evidence of procurement of drug substance with approval from DRAP.	The firm has submitted copy of letter No. 17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to import different API Strontium Ranelate for the purpose of test/analysis and stability studies is granted. The firm submitted that material was directly received at the plant. Import invoice is attached specifying import of Strontium ranelate 0.70 Kg (batch # STRHB200003).

Decision of 321st meeting: Deferred for submission of documents confirming import of API i.e., Goods declaration/ Airway bill/Courier receipt etc.

Firm's response: Firm has submitted copy of DHL Air Way Bill (9851092604) in name of M/s Himark Laboratories, declaring the contents as "Strontium ranelate".

Decision of 326th meeting: Approved.

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

16.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019. Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission	Dy. No. 24085 Dated: 01-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 21/06/2021
	The proposed proprietary name / brand name	**Trox 10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Cetirizine Dihydrochloride…….. 10 mg
	Pharmaceutical form of applied drug	White to off white round shaped without any score film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zirtek Allergy Relief 10 mg film-coated tablets by M/s UCB Pharma, MHRA Approved.
	For generic drugs (me-too status)	Avec 10mg Tablet by M/s Platinum Pharma, (Reg # 025506)
	Name and address of API manufacturer.	M/s Supriya Life sciences Ltd., Mumbai, INDIA. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (SLL/CTR/0309047, SLL/CTR/0309048, SLL/CTR/0309047).
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against that is **Zyrtec 10 mg Tab** by GSK Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Zyrtec 10 mg Tab** by GSK Pharma in acidic media (pH 1.2) & phosphate buffer (pH 4.5 & 6.8). The values for f_2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Supriya Lifescience Ltd., Mumbai, INDIA. A-5/2, Lote Parshuram Industrial Area, M.I.D.C Taluka – Khed, District – Ratnagiri, Maharashtra, India 415 722.		
API Lot No.	CTZ/083/20-21		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-94	T-95	T-96
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	15-10-2020	15-10-2020	15-10-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/103995/2021/11/38094 issued by Food and Drug Administration Maharashtra, India valid till 23-11-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 wherein the permission to import different APIs Cetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches alongwith chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.

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

Sr. No.	Observations	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by both Drug substance & Drug Product.	The firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameter were not provided.
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	The firm has submitted analytical method verification parameter of drug substance performed by drug product manufacturer. However, the specificity results were not presented. The relevant chromatograms of tested parameters were not provided.
4.	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	The firm has submitted pharmaceutical equivalence with comparator product Osstium Sachet of M/s Atco Labs.
5.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided.	Applicant batch no.: Trox 10mg Tab = T-94 Comparator batch no.: Zyrtec 10mg Tab = 354 E
6.	Control of excipients is missing.	The firm has submitted that excipients used in the formulation are of pharmacopoeial grade and we are using BP specifications
7.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug product shall be submitted.	The firm has not submitted analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) for drug product.
8.	Provide raw data sheets wherein details of sample solution preparation and standard solution and calculation formula for the assay test shall be mentioned.	The firm has submitted raw data sheets for the assay test.
9.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	Not submitted.
10.	UV spectra of dissolution data are required to be provided.	Not submitted.
11.	Justification is required for submission of single chromatogram as test result for each batch at different time intervals.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.

Deferred for submission of following:

Sr. No.	Decision of 316th meeting of RB	Response by the firm
1.	Analytical method verification report of drug substance performed by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.	The firm has submitted analytical method verification reports of drug substance by performing precision, linearity, accuracy, specificity and system suitability studies.
2.	HPLC chromatograms of all time points of real time and accelerated stability studies.	The firm has submitted HPLC chromatograms of real time and accelerated stability studies for 0, 3 and 6-month time point.
3.	UV spectra of dissolution testing, as recommended by the BP monograph of applied formulation, at all time points of stability study data.	Our UV-spectrophotometer (Insmark 300/2) was not software base due to which prints cannot be taken. Now we have purchased new software of UV-spectrophotometer with print option. Now the firm has submitted UV spectra of dissolution testing of stability batches.
4.	Analytical method verification reports of drug product performed by drug product manufacturer.	Analytical method verification reports of drug product have been provided by performing precision, linearity, accuracy, specificity and system suitability studies.
5.	Evidence of procurement of drug substance with approval from DRAP.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 wherein the permission to import different APIs Cetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted. The firm submitted that material was directly received at the plant. Import invoice is attached specifying import of Cetirizine dihydrochloride 0.07 Kg (batch # CTZ/083/20-21).

Decision of 321st meeting: Deferred for submission of documents confirming import of API i.e., Goods declaration/ Airway bill/Courier receipt etc.

Firm's response: Firm has submitted copy of DHL Air Way Bill (4320168341) in name of M/s Himark Laboratories from M/s Supriya Lifesciences.

Decision of 326th meeting: Approved.

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

Registration Board further advised to send a reference to QA & LT Division for verification of the submitted data of applied formulation during any upcoming inspection of the firm.

Case No. 02 Registration applications submitted along with stability studies data

17.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals (Pvt.) LTD. Plot No. 539-A Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	LURAX 80mg Tab
	Composition	Each Film Coated Tablet contains: Lurasidone Hydrochloride …… 80 mg
	Diary No. Date of R& I & fee	Dy. No 464 dated 17-11-2016 Rs.50,000/- Dated 09-11-2016,
	Pharmacological Group	Atypical Antipsychotic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	
	GMP status	Last inspection conducted on 29-03-2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
18.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals (Pvt.) LTD. Plot No. 539-A Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	LURAX 40mg Tab
	Composition	Each Film Coated Tablet contains: Lurasidone Hydrochloride …… 40 mg
	Diary No. Date of R& I & fee	Dy. No 468 dated 17-11-2016 Rs.50,000/- Dated 09-11-2016,
	Pharmacological Group	Atypical Antipsychotic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection conducted on 29-03-2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Lurax Tablets		
Name of Manufacturer	M/s Genetics Pharmaceuticals (Pvt.) Ltd. Plot No. 539-A Sunder Industrial Estate, Lahore.		
Manufacturer of API	M/s MEGAFINE PHARMA (P) LTD. PLOT NO. 31 TO 35 & 48 TO 51, 5,26 & K/201, VILLAGE LAKHMAPUR TALUKA DINDORI, NASHIK 422202		
API Lot No.	LUR/A620/III/89		
Description of Pack (Container closure system)	Alu-Alu blisters packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,3,6 months		
Batch No.	Batch No	Batch Size	Manufacturing Date
Lurax 80mg tablet	T-LD-01, T-LD-02, T-LD-03	2500 tablets each	April-2019
Lurax 40mg tablet	T-LU-01, T-LU-02, T-LU-03	2500 tablets	April-2019
Date of Initiation	April-2019	April-2019	April-2019
No. of Batches	03		
Date of Submission	20-11-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate issued by FDA Maharashtra in the name of M/s MEGAFINE PHARMA (P) LTD. PLOT NO. 31 TO 35 & 48 TO 51, 5,26 & K/201, VILLAGE LAKHMAPUR TALUKA DINDORI, NASHIK 422202 valid upto 12-02-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

Documents confirming import of API etc.	• Copy of invoice (Invoice No. 2/ME/AP17180300) for 2.4Kg of Lurasidone HCl has been submitted attested by Assistant Director DRAP, Lahore dated 13-04-2018.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Firm had initially submitted stability studies data with sampling time of 30 minutes in dissolution test, while upon inquiring about variation form the reference product in this regard, firm has also submitted dissolution results at 20minutes sampling time, for the same stability studies.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Lurax 40 mg (Lurasidone hydrochloride) Tablet and Lurax 80mg (Lurasidone hydrochloride) Tablet by M/s. Genetics Pharmaceuticals (Pvt.) ltd. Plot No. 539-A, Sunder Industrial Estate, Lahore.

Reference No: F.1-2/2020-PEC dated 6th July, 2019.
Investigation Date and Time: 21st- 22nd September, 2020.
Investigation Site: Factory premises of M/s. Genetics Pharmaceuticals (Pvt.) ltd. Plot No. 539-A, Sunder Industrial Estate, Lahore.

Composition of Panel:

1. Mr. Shaheen Iqbal, (Director, DTL Lahore)
2. Ms. Ayesha Irfan (FID, DRAP, Lahore).
3. Mr. Ammar Ashraf Awan, (Assistant Director (PEC) DRAP, Islamabad.)

Scope of investigation:

- Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.
- Performance of dissolution test with sampling time of 20 minutes at every time point of stability studies for both Lurax 40mg & Lurax 80mg tablet.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation have been summarized as under:

Q.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	Copy of invoice (Invoice No. 2/ME/AP17180300) for 2.4Kg of Lurasidone HCl from M/s MEGAFINE PHARMA (P) LTD. PLOT NO. 31 TO 35 & 48 TO 51, 5,26 & K/201, VILLAGE LAKHMAPUR TALUKA DINDORI, NASHIK 422202, attested by Assistant Director DRAP, Lahore dated 13-04-2018, was presented.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm submitted that the API manufacturer was selected based upon Desk evaluation wherein availability of the GMP certificate of API manufacturer, provision of DMG and working standards were considered.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has submitted AD I&E attested invoice (Invoice# 1819210038) dated 29-05-2018 for the procurement of reference standards.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has submitted certificates of analysis for API (batch# LUR/A620/III/89) and reference standards.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has provided copy of GMP certificate issued by FDA Maharashtra in the name of M/s MEGAFINE PHARMA (P) LTD. PLOT NO. 31 TO 35 & 48 TO 51, 5,26 & K/201, VILLAGE LAKHMAPUR TALUKA DINDORI, NASHIK 422202 valid upto 12-02-2022.

6.	Do you use API manufacturer method of testing?	• Firm has applied API manufacturer's method for the analysis of Lurasidone HCl. • *From available record it was identified that in the API manufacturer's method of analysis of Lurasidone, the retention time of API peak was recommended at about 8.5 minutes but in Genetics Pharmaceutical Pvt. Ltd. analysis of Lurasidone, the retention time of the peak was about 11 minutes.*
7.	Do you have stability studies reports on API?	The firm has submitted stability studies reports for both Accelerated & Long term conditions (as per Zone IV-a) from pellet manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of has quantified degradation productions during stability studies.
9.	Do you have method for quantifying the impurities in the API?	Firm has referred to API manufacturer's analytical method wherein procedure for quantification of impurities has been described but from the available analytical record it was identified that *there was difference of the relative retention times of impurities, between that mentioned in the API manufacturer's method and that performed by the applicant.*
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some remaining quantity of API which was available in the raw material store. Firm has used working standard for stability trials testing and some quantity of it was still available.
11.	Have you used pharmaceutical grade excipient?	All the excipients used in the formulation of Lurax tablets were of Pharmaceutical grade.
12.	Do you have documents confirming the import of the used excipient?	Invoices for the procurement of used excipients were presented.
13.	Do you have test reports and other records on the excipient used?	Relevant analytical record was available for the analysis of excipients.
14.	Do you have written and authorized protocols for the development of product?	Firm has presented general SOP for product development (document # GP-IMS-ISP-019-A). *Firm was advised to develop product specific protocol in future.*
15.	Have you performed Drug-excipient compatibility studies?	Firm has submitted that their formulation is qualitatively similar to that of the innovator product hence Drug-excipient compatibility study was not performed.
16.	Have you performed comparative dissolution studies?	Firm has submitted comparative dissolution studies against the reference product for both 40 mg & 80 mg strengths. • Comparative dissolution studies have been performed in following mediums: a. pH 1.2 buffer of 0.1N HCl b. pH 4.5 acetate buffer. c. pH 6.8 phosphate buffer. • Firm has submitted results for the CDP study showing comparable dissolution profile.
17.	Do you have product development (R&D) section	Firm has research and development department.
18.	Do you have necessary equipments available in product development section for development of product?	Firm has performed mixing in the lab scale mixer installed in the R&D section, while compression was performed using the facility of "Tablet general section".
19.	Are the equipments in product development section qualified?	The equipments used in the trial work were qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Firm has established proper maintenance / calibration / re-qualification program for the equipments used in the manufacturing of trial batches.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff (4 members) in Research and development

22.	Have you manufactured three stability batches for the stability studies of product as required?	Firm manufactured three stability batches for the stability studies as per requirement.
23.	What were the criteria for fixing the batch size of stability batches?	Firm has manufactured stability batches considering the quantity of dosage units required to complete long term stability studies till claimed shelf life.
24.	Do you have complete record of production of stability batches?	Complete batch manufacturing record, including dispensing, mixing, compression and packaging was verified from the relevant log books. Batch details were same as submitted earlier by the firm.
25.	Do you have protocols for stability testing of stability batches?	Firm has presented SOP for stability study protocol: Lurasidone 40mg tablet (GP-RND-SSP-041) Lurasidone 80mg tablet (GP-RND-SSP-042) *Firm was advised to include product specifications in the stability study protocol.*
26.	Do you have developed and validated the method for testing of stability batches?	Firm has validated the method for Assay test used for the performance of stability studies.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Firm has qualified equipments / instruments which were used for the testing of API and finished product. *Firm was advised to get instrument qualification studies from third party source having valid recognition for this purpose.*
29.	Do your method of analysis stability indicating?	Firm has referred to test of specificity & forced degradation, performed during method validation to establish that the Assay test method is stability indicating.
30.	Do your HPLC software is 21CFR compliant?	Firm has used two different Agilent HPLCs, for the performance of Raw material & stability studies analysis, details of which are as under: i. Agilent 1260 Infinity II (open lab) (Equipment ID: GP-QC-HPLC-035, used for raw material analysis) ii. Agilent 1260 Infinity II (open lab) (Equipment ID: GP-RND-HPLC-001, used for FPP analysis) Both the systems could not be rated as 21 CFR compliant because of the following reasons: a) Date & time of the system were not locked and could be changed without any administrative control. b) The rights of the manager and analyst were not defined. c) The audit trail feature could be activated or de-.activated prior to any analysis. d) There was no control applied on the deletion of any file.
31.	Can you show Audit Trail reports on product testing?	Firm has demonstrated audit trail reports for the submitted stability studies data. Also the relevant log books were verified for the performance of stability studies.
32.	Do you have some remaining quantities of degradation products and stability batches?	Firm have the remaining quantities of stability batches which were verified.
33.	Do you have commitment batches kept on stability testing?	The firm has kept the remaining quantities of all batches in stability chamber for on-going real time stability study, which were verified.
34.	Do you have valid calibration status for the equipments used in production and analysis of applied product?	The calibration status of the equipments used in the manufacturing and testing of the stability batches were checked and found within their due date. The equipments were properly labeled for the current status of calibration and maintenance.
35.	Do Proper and Continuous monitoring and control are available for stability chamber?	• The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and digital data loggers. Records of digital data logger for both

		chambers used in accelerated and real time stability studies were demonstrated. • Details of capacity of each chamber are as under: Chamber volume: 749litre Max. no of sliding grids: 14 Max. load per appliance : 300 kg
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	All related manufacturing area, equipment, personnel and utilities are as per cGMP compliance. Moreover firm was advised as under; a. To strengthen their in-process Quality Assurance System, especially for the Raw material store. b. To enhance their manufacturing capacity, considering the number of already registered products and those which have been applied for registration.
Additional Questions referred to panel		
37.	Performance of dissolution test with sampling time of 20 minutes at every time point of stability studies for both Lurax 40mg & Lurax 80mg tablet.	The firm could not establish the performance of dissolution test with sampling time of 20 minutes at every time point of stability studies for both Lurax 40mg & Lurax 80mg tablet and following was observed in this regard: • The finished product testing method does not mention the performance of dissolution test at 20minutes time point. • Firm could not establish the performance of said study at every time point, from the equipment log book of UV spectrophotometer. • When one of the UV spectrophotometer report, for the performance of dissolution analysis at 20 minutes time point, was evaluated from the computer system it was observed that the date of creation of that file was subsequent to the date of modification, which established the fact that the said performance report has been created by changing the time & date of system. • Also the UV spectrophotometer system had no control overtime & date and the UV spectrophotometer reports were editable for any sort of details.

Conclusion:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. Genetics Pharmaceuticals (Pvt.) ltd. Plot No. 539-A, Sunder Industrial Estate, Lahore have conducted stability studies of the following products.

Lurax 40mg Tablet
Lurax 80mg Tablet

However, few points are being recorded for the kind perusal of the Drug Registration Board, against questions **6, 9** and **37** of the above check list.

Decision of 297th meeting: Registration Board deferred the applications of Lurax 40mg tablet & Lurax 80mg tablet and decided to verify of following by panel to be constituted by Chairman Registration Board:

- Performance of dissolution test with sampling time of 20 minutes at time points of 9th month & onward, of long-term stability studies.

Evaluation by PEC: With reference to above cited decision on site inspection of M/s Genetics Pharmaceuticals (Pvt.) Ltd. Plot No. 539-A, Sundar Industrial Estate, Lahore was conducted on 27-01-2023, report of which is presented below:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Lurax 40 mg (Lurasidone hydrochloride) Tablet and Lurax 80mg (Lurasidone hydrochloride) Tablet by M/s. Genetics Pharmaceuticals (Pvt.) Ltd. Plot No. 539-A, Sundar Industrial Estate, Lahore.

Reference No.: No. F.1-2/2020-PEC dated: 24th March, 2021.
Investigation Date and Time: 27th January, 2023
Investigation Site: Factory premises of M/s. Genetics Pharmaceuticals (Pvt.) Ltd. Plot No. 539-A, Sundar Industrial Estate, Lahore.

Composition of Panel:

1. Dr. Muhammad Munawar Hayat, (Director, DTL Lahore)
2. Mr. Sheikh Rasheed (FID, DRAP, Lahore).
3. Mr. Akbar Ali, (Deputy Director (PEC) DRAP, Islamabad.)

Scope of investigation:

- Performance of dissolution test with sampling time of 20 minutes at 9 months and onward of stability studies for both Lurax 40mg & Lurax 80mg tablet.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation have been summarized as under:

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API including approval from DRAP?	Copy of invoice (Invoice No. 2/ME/AP17180300) for 2.4Kg of Lurasidone HCl from M/s MEGAFINE PHARMA (P) LTD. PLOT NO. 31 TO 35 & 48 TO 51, 5,26 & K/201, VILLAGE LAKHMAPUR TALUKA DINDORI, NASHIK 422202, attested by Assistant Director DRAP, Lahore dated 13-04-2018, was presented
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm submitted that the API manufacturer was selected based upon Desk evaluation wherein availability of the GMP certificate of API manufacturer, provision of DMG and working standards were considered.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has submitted AD I&E attested invoice (Invoice# 1819210038) dated 29-05-2018 for the procurement of reference standards.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has submitted certificates of analysis for API (batch# LUR/A620/III/89) and reference standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has provided copy of GMP certificate issued by FDA Maharashtra in the name of M/s MEGAFINE PHARMA (P) LTD. PLOT NO. 31 TO 35 & 48 TO 51, 5,26 & K/201, VILLAGE LAKHMAPUR TALUKA DINDORI, NASHIK 422202 valid upto: 26-5-2023.
6.	Do you use API manufacturer method of testing for testing API?	• Firm has applied API manufacturer's method for the analysis of Lurasidone HCl.
7.	Do you have stability studies reports on API?	The firm has submitted stability studies reports for both Accelerated & Long-term conditions (as per Zone IV-a) from API manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of has quantified degradation productions during stability studies.

9.	Do you have method for quantifying the impurities in the API?	Firm has referred to API manufacturer's analytical method wherein procedure for quantification of impurities has been described and firm has performed the API impurities quantification as per reference method of quantification from the API manufacturer.	
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some remaining quantity of API which was available in the raw material store. Firm has used working standard for stability trials testing and some quantity of it was still available	
11	Have you used pharmaceutical grade excipients?	All the excipients used in the formulation of Lurax tablets were of pharmaceutical grade.	
12	Do you have documents confirming the import of the used excipients?	Invoices for the procurement of used excipients were presented	
13	Do you have test reports and other records on the excipients used?	Relevant analytical record was available for the analysis of excipients	
14	Do you have written and authorized protocols for the development of Lurax 40mg & 80mg tablets?	Firm has Product Specific Protocol for both Lurax 40mg and 80mg Tablet.	
15	Have you performed Drug-excipient compatibility studies?	Firm has submitted that their formulation is qualitatively similar to that of the innovator product hence Drug-excipient compatibility study was not performed.	
16	Have you performed comparative dissolution studies?	Firm has submitted comparative dissolution studies against the reference product for both 40 mg & 80 mg strengths. • Comparative dissolution studies have been performed in following mediums: a. pH 1.2 buffer of 0.1N HCl b. pH 4.5 acetate buffer. c. pH 6.8 phosphate buffer. d. pH 3.8 McLaren Buffer • Firm has submitted results for the CDP study showing comparable dissolution profile.	
17	Do you have product development (R&D) section?	Firm has research and development department.	
18	Do you have necessary equipments available in product development section for development of tablets?	Firm has performed mixing in the lab scale mixer installed in the R&D section, while compression was performed using the facility of "Tablet general section".	
19	Are the equipments in product development section qualified?	The equipments used in the trial work were qualified.	
20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Firm has established proper maintenance / calibration / re-qualification program for the equipments used in the manufacturing of trial batches.	
21	Do you have qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff (6 members) in Research and development	

	22	Have you manufactured three stability batches for the stability studies of tablets as required?	Firm manufactured three stability batches for the stability studies as per requirement
	23	Do you have any criteria for fixing the batch size of stability batches?	Firm has manufactured stability batches considering the quantity of dosage units required to complete long term stability studies till claimed shelf life.
	24	Do you have complete record of production of stability batches?	Complete batch manufacturing record, including dispensing, mixing, compression and packaging was verified from the relevant log books. Batch details were same as submitted earlier by the firm *Firm has performed disintegration time as not more than 30minutes whereas dissolution time was established as 20minutes, Firm was advised to revise the disintegration time in view of 20 minutes; Results are within the Range i.e. 6 minutes*
	25	Do you have protocols for stability testing of stability batches?	Firm has presented SOP for stability study protocol: Lurasidone 40mg tablet (GP-RND-SSP-041) Lurasidone 80mg tablet (GP-RND-SSP-042).
	26	Do you have developed and validated the method for testing of stability batches?	Firm has validated the method for Assay test used for the performance of stability studies.
	27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
	28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Firm has qualified equipments / instruments which were used for the testing of API and finished product.
	29	Do your method of analysis stability indicating?	Firm has referred to test of specificity & forced degradation, performed during method validation to establish that the Assay test method is stability indicating.
	30	Do your HPLC software 21CFR Compliant?	Firm has used two different Agilent HPLCs, for the performance of Raw material & stability studies analysis, details of which are as under: i. Agilent 1260 Infinity II (open lab) (Equipment ID: GP-QC-HPLC-035, used for raw material analysis) ii. Agilent 1260 Infinity II (open lab) (Equipment ID: GP-RND-HPLC-001, used for FPP analysis) Both the systems are 21 CFR compliant.
	31	Can you show Audit trail reports on testing	Firm has demonstrated audit trail reports for the submitted stability studies data. Also the relevant log books were verified for the performance of stability studies

32	Do you have some remaining quantities of degradation products and stability batches?	Firm have the remaining quantities of stability batches which were verified.
33	Do you have stability batches kept on stability testing?	The firm has completed stability studies (Both Accelerated and Real Time) up to Shelf Life of both Lurax 40mg & 80mg Tablet.
34	Do you have valid calibration status for the equipments used in tablets production and analysis?	The calibration status of the equipments used in the manufacturing and testing of the stability batches were checked and found within their due date. The equipments were properly labelled for the current status of calibration and maintenance.
35	Do proper and continuous monitoring and control are available for stability chamber?	• The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and digital data loggers. Records of digital data logger for both chambers used in accelerated and real time stability studies were demonstrated. • Details of capacity of each chamber are as under: Chamber volume: 749litre Max. no of sliding grids: 164 Max. load per appliance: 300 kg
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	All related manufacturing area, equipment, personnel and utilities are as per cGMP compliance.

Conclusion:
Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, it is concluded that M/s. Genetics Pharmaceuticals (Pvt.) ltd. Plot No. 539-A, Sunder Industrial Estate, Lahore have conducted dissolution test with sampling time of 20 minutes at 9 months and onward of stability studies of both products i.e.;

i. Lurax 40mg Tablet
ii. Lurax 80mg Tablet

Decision of 326th meeting: Registration Board Approved the applications of LURAX 40mg Tab & LURAX 80mg Tab with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications for each strnegth 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.**

Case No. 03 Registration applications of newly granted DML or New section (Human)

New Section

M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore The Central Licensing Board in its 286th meeting held on 11th May, 2022 has considered and approved the grant of Drug Manufacturing License to M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore by way of Formulation vide approval letter No. F. 1-10/2012-Lic dated 7th June, 2022 with following (06) sections.

S No.	Section
1	Dry Powder Suspension (Cephalosporin) Section
2	Capsule (Cephalosporin) Section
3	Dry Powder Injection (Cephalosporin) Section

19.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 37580 dated 23-12-2022
	Details of fee submitted	Rs.30,000/- dated 15-12-2022
	The proposed proprietary name / brand name	**Welcef 250mg IM injection**
	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	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Oxidil 250mg IM injection by M/s Sami Pharmaceuticals (Pvt.)Ltd, Reg. No. 023073
	For generic drugs (me-too status)	Rocephin injection 250mg IM by M/s F.Hoffman-La Roche Ltd. Basel, Switzerland, USFDA Approved.
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	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 as submitted detail of nomenclature, structure, general properties, solubilities, physical

		form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (Q012008048, Q012008049, Q012008050)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Oxidil 250mg IM Injection by Sami Pharmaceuticals (Pvt) Ltd. by performing quality tests (Identification, PH, 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. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
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.	TCC001	TCC002	TCC003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	09-05-22	10-05-22	11-05-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by People's republic of China valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including

		Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Firm has submitted clearance no. E-533464883684 for 500Kg of Ceftriaxone sodium issued in name of M.s Medisave by AD I&E DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
20.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31340 dated 02-11-2022
	Details of fee submitted	Rs.30,000/- dated 29-10-2022
	The proposed proprietary name / brand name	**Welcef 1g IM injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…1g
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Rocephin injection 1g IM by M/s F.Hoffman-La Roche Ltd. Basel, Switzerland, USFDA Approved. Reg. No.008436
	For generic drugs (me-too status)	Rocephin injection 1g IM by M/s F.Hoffman-La Roche Ltd. Basel, Switzerland, Reg. No.008436
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21

	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	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 as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (Q012008048, Q012008049, Q012008050)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Rocephin injection 1g IM by M/s F.Hoffman-La Roche Ltd. Basel, Switzerland by performing quality tests (Identification, PH, 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. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
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.	TCV001	TCV002	TCV003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	05-2022	05-2022	05-2022

Date of Initiation		19-05-22	20-05-22	21-05-22
No. of Batches		03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by People's republic of China valid till 05/06/2023.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Firm has submitted clearance no. E-533464883684 for 500Kg of Ceftriaxone sodium issued in name of M.s Medisave by AD I&E DRAP, Lahore.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Evaluator:			
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			
21.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.	
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 37581; dated 23/12/2022.	
	Details of fee submitted	PKR 30,000/-: vide slip No.17371144 dated 15/12/2022.	
	The proposed proprietary name / brand name	Ceftriaxone for 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	Dry powder injection (IM).
	Pharmacotherapeutic Group of (API)	Third generation Cephalosporin Antibiotics.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Rocephin injection 250mg, 500mg, 1g, and 2gm IV, IM USFDA Approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Oxidil 500mg IM injection, M/s Sami Pharmaceuticals, Reg. No. 023073.
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) - New section vide No.F.1-10/2012-Lic dated 07-06-2022 is approved.
	Name and address of API manufacturer.	M/s. Sinopharm Weiqida Pharmaceutical Co., Ltd., Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China. Copy of GMP certificate No. SX20180229 dated 06-06-2018 issued by Shanxi Province Food and Drug Administration valid till 05-06-2023 is submitted.
	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 Ceftriaxone sodium is present in USP. The firm as submitted detail of drug substance regarding its 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 (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH for 06 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: (Q012007053, Q012008001, Q012008002)
	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	Pharmaceutical Equivalence have been established against

	dissolution profile	the brand leader that is Oxidil 500mg IM Injection by Sami Pharmaceuticals (Pvt.) Ltd. by performing quality tests (Identification, Average weight content & 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. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
Description of Pack (Container closure system)	1x10ml vial containing Ceftriaxone for Injection with constituent Diluent.		
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.	TCB001	TCB002	TCB003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	16-05-22	17-05-22	18-05-22
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.	Copy of GMP certificate No. SX20180229 issued by People's republic of China valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Firm has submitted clearance no. E-533464883684 for 500Kg of Ceftriaxone sodium issued in name of M.s Medisave by AD I&E DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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 by the Evaluator:

- Justification for not performing PE against innovator product.

Firm's response:

Firm has submitted new Pharmaceutical equivalence studies against the Rocephin 500mg injection.

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.**

22.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34506 dated 29-11-2022
	Details of fee submitted	Rs.30,000/- dated 25-11-2022
	The proposed proprietary name / brand name	Myxim 200mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Capsule contains:** Cefixime(as trihydrate)……..200mg
	Pharmaceutical form of applied drug	Oral Capsule (cephalosporin)
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	In-house
	Proposed Pack size	1x5's,1x10's, 2x5's As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefim 200mg Capsule by M/s Hilton pharmaceuticals Pvt Ltd. Registration #: 034664
	For generic drugs (me-too status)	Isocef 200mg capsule by M/s Sharooq phamaceuticals pvt Ltd USFDA Approved
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime 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 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00244/135/2010, *00243/136/2010*, *00244/137/2010*)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Cefim 200mg Capsule by Hilton pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, and Uniformity of the dosage form). CDP has been performed against the same brand that is Cefim 200mg Capsule by Hilton pharmaceuticals in Acid media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan		
API Lot No.	00244/021/2022		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCM001	TCM002	TCM003
Batch Size	470Capsules	470Capsules	470Capsules
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	21-05-22	22-05-22	23-05-22
No. of Batches	03		

Administrative Portion

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) issued by Drug regulatory Authority of Pakistan(Government of Pakistan) valid till 26/06/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator: Firm has submitted stability studies as per the monograph approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.		
Decision: Approved with manufacturer specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022. 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.		
23.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34507 dated 29-11-2022
	Details of fee submitted	Rs.30,000/- dated 25-11-2022
	The proposed proprietary name / brand name	**Myxim 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Capsule contains:** Cefixime(as trihydrate)……..400mg
	Pharmaceutical form of applied drug	Oral Capsule (cephalosporin)
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	In-house
	Proposed Pack size	1x5's,1x10's, 2x5's As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cebosh 400mg Capsule by M/s BOSCH Pharmaceuticals Pvt Ltd Registration #: 027160
	For generic drugs (me-too status)	Cefspan 400mg capsule by M/s Barret Hodgson Pakistan(Pvt) Ltd USFDA Approved
	GMP status of the Finished product manufacturer	

		GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime 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 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00244/135/2010, *00243/136/2010*, *00244/137/2010*)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Cebosh 400mg Capsule by M/s BOSCH Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, and Uniformity of the dosage form). CDP has been performed against the same brand that is Cebosh 400mg Capsule by M/s BOSCH Pharmaceuticals in Acid media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited Address: Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan
API Lot No.	00244/021/2022
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	TCX001	TCX002	TCX003
Batch Size	470Capsules	470Capsules	470Capsules
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	18-05-22	19-05-22	20-05-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) issued by Drug regulatory Authority of Pakistan(Government of Pakistan) valid till 26/06/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator: Firm has submitted stability studies as per the monograph approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

Observations	**Firm's response**
Justification shall be submitted for not performing Pharmaceutical equivalence & CDP studies against the innovator product	Firm has submitted new Pharmaceutical equivalence and CDP studies against the Cefspan suspension for the 400mg strength.

Decision: Approved with manufacturer specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022. 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.

24.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No 34705 dated 30-11-2022
	Details of fee submitted	Rs.30,000/- dated 25-11-2022
	The proposed proprietary name / brand name	Myxim DS 200mg/5ml Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml contains:** Cefixime(as trihydrate)……..200mg

	Pharmaceutical form of applied drug	Dry Powder Suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1x30ml,1x60ml As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefspan DS 200mg/5ml Powder for Oral Suspension by M/s Barret Hodgson Pakistan (Pvt) Ltd Registration #: 024634
	For generic drugs (me-too status)	Suprax 200mg/5mL Powder for Paediatric Oral Suspension by M/s Merck Farma y Quimica, S.A. Poligono Merck, 08100 Mollet del Valles (Barcelona), Spain USFDA Approved
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	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: (00244/135/2010, *00243/136/2010*, *00244/137/2010*)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Cefspan DS 200mg/5ml Powder for Oral Suspension by M/s Barret Hodgson by performing quality tests (Identification, Assay, Dissolution, and Uniformity of the dosage form). CDP has been performed against the same brand that is Cefspan DS 200mg/5ml Powder for Oral Suspension by M/s Barret Hodgson in Acid media (pH-1.2),

		Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan		
API Lot No.		00243/081/2022		
Description of Pack (Container closure system)		Unit carton containing 01 amber glass bottle with proper label further (1x1's) packed in unit carton with leaflet 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, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		TCF001	TCF002	TCF003
Batch Size		160bottles	160bottles	160bottles
Manufacturing Date		05-2022	05-2022	05-2022
Date of Initiation		21-05-22	23-05-22	24-05-22
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) issued by Drug regulatory Authority of Pakistan(Government of Pakistan) valid till 26/06/2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of Evaluator:				
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**				
25.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore		
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore		

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34704 dated 30-11-2022
	Details of fee submitted	Rs.30,000/- dated 25-11-2022
	The proposed proprietary name / brand name	Myxim 100mg/5ml Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each 5ml contains:** Cefixime(as trihydrate) ……..100mg
	Pharmaceutical form of applied drug	Dry Powder Suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1x30ml,1x60ml As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefspan 100mg/5ml Powder for Oral Suspension by M/s Barret Hodgson Pakistan (Pvt) Ltd Registration #: 010429
	For generic drugs (me-too status)	Suprax 100mg/5mL Powder for Paediatric Oral Suspension by M/s Merck Farma y Quimica, S.A. Poligono Merck, 08100 Mollet del Valles (Barcelona), Spain USFDA Approved
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefixime is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	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: (00244/135/2010, *00243/136/2010*, *00244/137/2010*)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Cefspan 100mg/5ml Powder for Oral Suspension by M/s Barret Hodgson by performing quality tests (Identification, Assay, Dissolution, and Uniformity of the dosage form). CDP has been performed against the same brand that is Cefspan 100mg/5ml Powder for Oral Suspension by M/s Barret Hodgson in Acid media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/S Pharmagen Limited **Address:** Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. Pakistan		
API Lot No.	00243/081/2022		
Description of Pack (Container closure system)	Unit carton containing 01 amber glass bottle with proper label further (1x1's) packed in unit carton with leaflet 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, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCE001	TCE002	TCE003
Batch Size	160bottles	160bottles	160bottles
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	18-05-22	19-05-22	20-05-22
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) issued by Drug regulatory Authority of Pakistan(Government of Pakistan) valid till 26/06/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks of Evaluator:

Observations	**Firm's response**
Details of reconstitution diluent shall be provided.	Firm has submitted water as reconstitution diluent.
In-use stability studies shall be submitted.	Firm has submitted in-use stability studies for the re constituted suspension of both 100mg & 200mg strength.

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.**

26.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceutical 19 km, Sheikhupura Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceutical 19 km, Sheikhupura Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on 03.01.2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 07.07.2020 which specifies Dry Powder Injectable (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 30789 dated 07-11-2022
	Details of fee submitted	Rs.30,000/- dated 07-11-2022
	The proposed proprietary name / brand name	**Sonnet 2g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium equivalent to Ceftriaxone …….2000 mg
	Pharmaceutical form of applied drug	IV Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibacterial
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1x 1's Vial & 1x5's Vial
	Proposed unit price	As Per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Oxidil Injection 2G IV of SAMI Pharmaceutical (Pvt.) LTD., Reg # 086609
	Name and address of API manufacturer.	HENAN KANGDA PHARMACEUTICAL CO., LTD. Block no.66 Jing wu Road, Xiang cheng City, Henan, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance(Conditions duration of Stability studies)	**Ceftriaxone Sodium:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies s against the reference product of "Oxidil Injection 2gm IV".
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA			
Manufacturer of APIs	M/s. Henan Kangda Pharmaceutical Co., Ltd. Block no.66 Jing Wu Road, Xiang Cheng City, Henan, China.		
API Lot No.	2022009013		
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.	T-001	T-002	T-003
Batch Size	300 Vials	300 Vials	300 Vials
Manufacturing Date	26.06.2022	26.06.2022	26.06.2022

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer	Copy of DML (Certificate# Yu20150186) issued by Henan Provincial Drug Administration valid upto 13-12-2025

<table>
<tr><td></td><td>issued by concerned regulatory authority of country of origin.</td><td></td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Lahore has been submitted.
Ceftriaxone Sodium:
<table>
<tr><th>Batch No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>2022009013</td><td>3.5Kg</td><td>27.07.2020</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data pf stability batches along with batch manufacturing record and analytical record.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">Remarks of Evaluator:</td></tr>
<tr><td colspan="3">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.</td></tr>
</table>

Case no. 04 Registration Applications of Import drug products:

a. Deferred cases (Veterinary):

27.	**Name and address of Applicant**	M/s Atzan Pharmaceuticals, commercial area aziz Bhatti town Sargodha
	Detail of Drug Sale License	DSL No. 0011000 0001644 valid up 14-Apr-2020
	Name and address of manufacturer	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company, Lot D1-D4 Dong Tho Industrial Complex, Yen Phong District, BAC Ninh Province, Vietnam.
	Marketing authorization holder	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company, Lot D1-D4 Dong Tho Industrial Complex, Yen Phong District, BAC Ninh Province, Vietnam.
	Name of exporting country	Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 23395 Dated 07-12-2017
	Fee including differential fee	Rs. 100,000/- Dated 07-12-2017
	Brand Name +Dosage Form + Strength	Cefquin 2.5 LA suspension for injection
	Composition	Each ml of suspension contains; Cefquinome as sulfate……..25mg
	Finished Product Specification	In-House
	Pharmacological Group	Antiobiotic
	Shelf life	24 months
	Demanded Price	Decontrolled.
	Pack size	1's (type I glass vial)
	Me-too status	COBACTAN 2.5% SUSPENSION FOR INJECTION (50mL), Reg. No. 078219

Stability studies	Firm has submitted long term (24 months) at 30ºC 65±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Ministry of Agriculture and Rural Development, Department of Animal Health Vietnam (certificate no. 494/2017/QLT-CFS) dated 26/06/2017 is submitted. ➢ Copy of GMP certificate (No.23/22/GCN-GMP) dated 25/07/2022 issued by Ministry of Agriculture and Rural Development. The certificate is valid for 05 years. **As per copy of GMP certificate the manufacturer has production lines of Beta-Lactam in the form suspension for Injection.** ➢ Copy of authorization letter is submitted through which M/s Atzan Pharmaceuticals is appointed as agent for different products including the applied product.

Remarks of the Evaluator:

Observations	Response
Since registration of injections is granted with 01filled volume but you have applied for 03, therefore, select 01 filled volume of the applied product along with the stability study data conducted under the conditions of zone IV-A of 03 batches of relevant filled volume, please. Moreover, provide me-too status of the applied product in same filled volume as selected.	The firm has requested for 50mL filled volume. Me too: COBACTAN 2.5% SUSPENSION FOR INJECTION (50mL), Reg. No. 078219
Submit valid copy of drug sale license.	The firm has submitted receipt for renewal of DSL. Ref No. 384-11940097-2022 Add: 13-E, Commercial area, Aziz Bhatti Town, District Sargodha.
Detail of primary packaging material is required.	Type I glass vial, 50mL.

Decision of 320th meeting: The Board discussed that B-Lactam preparations include Penicillin as well as Cephalosporin and submitted copy of GMP certificate does not clarify that the production lines of manufacturer are for Penicillin or Cephalosporin. Keeping in view, the Board decided to defer the case for further clarification of availability of manufacturing facility for the applied product.

Firm's reply:

We would like to provide the response of manufacturer to the honorable authority which is as following:

According to the regulations of the Vietnam Department of Animal Health, the GMP Certificate in Vietnam has the same standard format. There is no division into Penicillin line or Cephalosporin line, which means that the certificated company is allowed to produce both Betalactam product lines on that same line

However, if there is such a specific division in your country regulation, we would like to point out our ideas:

1 - The GMP certificate in Vietnam cannot be divided into parts, if necessary, Sakan Vietnam would like to request a document from the Department of Animal Health that it is allowed to produce both products on the same Betalactam line.

2 - If you request to produce those Penicillin or Cephalosporin products separately (but not to the extent that we have to have two separate production lines for it). In this case; we carry out batch production. Each batch will continuously produce one of the Penicillin or Cephalosporin products then sterilize the whole production line before switching to the other product.

Decision: Registration Board after thorough deliberation decided to defer the application, for availability of separate manufacturing facility for the applied formulation with reference ot the provisions of Drug L, R&A rules, 1976.

Case No. 01 Registration applications of Export facilitation cases

a. New Cases

Case No. 1: M/s Nabiqasim Industries (Pvt) Ltd. The following case was referred to PEC from Assistant Director PR-I/EFD vide letter No. F.1-6/2019-PR-I (EFD) dated 28-02-2023.		
28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries (Pvt) Ltd. 17/24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt) Ltd. 17/24 Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-05-2022 issued based on inspection dated 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020. The letter specifies Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 710 dated 09-01-2023
	Details of fee submitted	PKR 27,000/- Dated 08-12-2022 + PKR 48,000/- Dated 31-12-2022
	The proposed proprietary name / brand name	**AZILSAR 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 40mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	White to off white colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Ami Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT& Post: Karakhadi-391450, Taluka: Paura, District Vadodara. Gujarat, 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 drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet 40mg manufactured by Takeda Ireland Ltd.. Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 40mg in 4 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT& Post: Karakhadi-391450, Taluka: Paura, District Vadodara. Gujarat, India.		
API Lot No.	AZR/M-0010122		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	509DS01	509DS02	509DS03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	08-08-2022	08-08-2022	08-08-2022
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)	NA
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. 22043267) dated 18-04-2022 issued by Food and Drugs Control Administration Gujrat State India. The certificate is valid till 17-04-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import API Azilsartan medoxomil 0.5Kg dated 11-03-2022. Firm has also submitted copy of commercial invoice dated 25-02-2022 specifying 0.5Kg Azilsartan medoxomil, however the invoice is **NOT** cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not available
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of 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.	The sample and standard solution concentration for assay test of drug substance is 0.1mg/ml while in accuracy test in method verification studies you have performed the accuracy test within a concentration range of 0.5mg/ml to 1.5mg/ml taking 1mg/ml as 100%. Clarify in the light of applicable guidelines.	• As per method verification protocol of drug substance in assay testing method of drug substance nominal concentration of Analyte for standard and sample preparation is 0.1mg/ml, same concentration was used as 100% while preparing samples for evaluation of method verification studies. • During report compilation 1mg/ml concentration mention as 100% in accuracy parameter is a typo-graphical error. We acknowledge that 0.1mg/ml as 100% concentration, 0.05mg/ml as 50% concentration and 0.15mg/ml as 150% concentration is used for sample preparation. Revised Analytical Method verification report is provided by the firm.
2.	Submit clearance certificate or copy of commercial invoice cleared by AD (I&E) DRAP, since the submitted commercial invoice is not cleared by AD (I&E) DRAP.	Firm has submitted copy of License to import API Azilsartan medoxomil 0.5Kg dated 11-03-2022. Firm has also submitted copy of commercial invoice dated 25-02-2022 specifying 0.5Kg Azilsartan medoxomil, however the invoice is **NOT** cleared by AD (I&E) DRAP.
3.	Submit stability study data till 6 months, since the submitted data is till 3 months only.	Firm has submitted 6th month stability study data along with analytical record.
4.	Submit copy of BMR of three stability batches.	Firm has submitted copy of BMR of three stability batches.

Registration Board was apprised that the firm has also submitted copy of commercial invoice (No. EXP/1/21/-22/0727 dated 25-02-2022 along with copy of Goods Declaration with IGM No KPAF-1711-2022 dated 06-03-2022 and copy of airway bill number 176-3509 3914 dated 4th March 2022.

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.**		
29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries (Pvt) Ltd. 17/24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt) Ltd. 17/24 Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-05-2022 issued based on inspection dated 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 27-04-2020. The letter specifies Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 709 dated 09-01-2023
	Details of fee submitted	PKR 27,000/- Dated 08-12-2022 + PKR 48,000/- Dated 31-12-2022
	The proposed proprietary name / brand name	**AZILSAR 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 80mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	White to off white colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Ami Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT& Post: Karakhadi-391450, Taluka: Paura, District Vadodara. Gujarat, 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 drug substance data related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet 80mg manufactured by Takeda Ireland Ltd. Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 80mg in 4 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pvt Ltd. Block No.82/B, ECP Road, AT& Post: Karakhadi-391450, Taluka: Paura, District Vadodara. Gujarat, India.		
API Lot No.	AZR/M-0010122		
Description of Pack (Container closure system)	Alu-alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	504DS01	504DS02	504DS03
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	08-08-2022	08-08-2022	08-08-2022
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)	NA
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. 22043267) dated 18-04-2022 issued by Food and Drugs Control Administration Gujrat State India.

		The certificate is valid till 17-04-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of License to import API Azilsartan medoxomil 0.5Kg dated 11-03-2022. Firm has also submitted copy of commercial invoice dated 25-02-2022 specifying 0.5Kg Azilsartan medoxomil, however the invoice is **NOT** cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not available
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of 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.	The sample and standard solution concentration for assay test of drug substance is 0.1mg/ml while in accuracy test in method verification studies you have performed the accuracy test within a concentration range of 0.5mg/ml to 1.5mg/ml taking 1mg/ml as 100%. Clarify in the light of applicable guidelines.	• As per method verification protocol of drug substance in assay testing method of drug substance nominal concentration of Analyte for standard and sample preparation is 0.1mg/ml, same concentration was used as 100% while preparing samples for evaluation of method verification studies. • During report compilation 1mg/ml concentration mention as 100% in accuracy parameter is a typo-graphical error. We acknowledge that 0.1mg/ml as 100% concentration, 0.05mg/ml as 50% concentration and 0.15mg/ml as 150% concentration is used for sample preparation. Revised Analytical Method verification report is provided by the firm.
2.	Submit clearance certificate or copy of commercial invoice cleared by AD (I&E) DRAP, since the submitted commercial invoice is not cleared by AD (I&E) DRAP.	Firm has submitted copy of License to import API Azilsartan medoxomil 0.5Kg dated 11-03-2022. Firm has also submitted copy of commercial invoice dated 25-02-2022 specifying 0.5Kg Azilsartan medoxomil, however the invoice is **NOT** cleared by AD (I&E) DRAP.
3.	Submit stability study data till 6 months, since the submitted data is till 3 months only.	Firm has submitted 6th month stability study data along with analytical record.
4.	Submit copy of BMR of three stability batches.	Firm has submitted copy of BMR of three stability batches.

Registration Board was apprised that the firm has also submitted copy of commercial invoice (No. EXP/1/21/-22/0727 dated 25-02-2022 along with copy of Goods Declaration with IGM No KPAF-1711-2022 dated 06-03-2022 and copy of airway bill number 176-3509 3914 dated 4th March 2022.

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. 2: M/s AGP Limited.

The following case was referred to PEC from Assistant Director PR-I/EFD vide letter No. F.1-6/2019-PR-I (EFD) dated 12-01-2023.

30.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 25-08-2020 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** Firm has submitted copy of GMP certificate dated 11-11-2022 issued on the basis of inspection dated 11-10-2022.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 14295 dated 13-06-2022
	Details of fee submitted	PKR 75,000/- Dated 20-05-2022
	The proposed proprietary name / brand name	**CEBACTUM 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g (PMDA Japan Approved)
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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 their product against Cebac Injection of Bosch Pharm.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.		
API Lot No.	1091EJ81NE		
Description of Pack (Container closure system)	Glass Vials		
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	1000 vials	1000 vials	1000 vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board.

		• Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
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. SD20190876) issued by CFDA China is submitted by the firm. The certificate is valid till 21-04-2024. Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter of loan and memorandum of understanding with M/s Swiss Pharma for getting 10Kg loan of Cefoperazone sodium and sulbactam sodium. • Firm has submitted copy of invoice specifying import of 40Kg Cefoperazone sodium and sulbactam sodium by M/s Swiss Pharma. The invoice is cleared by AD (I&E) DRAP dated 11-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability 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:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the brand name of the applied product, since Cebactum injection is mentioned in few section while Parabactum Injection is mentioned in other sections.	Cebactum Injection is our proposed brand name while Parabactum is typographic mistake. The registered brand of the manufacturer is Cefbac injection and the attached stability data is of cefbac injection.
2.	Specify the exact source of drug substance including complete address, since the submitted document is in chinese language and are not readable.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.
3.	Submit complete module 3.2.S as per CTD guidance document since the submitted documents are not aligned as recommended in the guidance document.	Firm has submitted complete module 3.2.S as per the guidance document approved by Registration Board.
4.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of	Firm has submitted specifications of API and its analytical method from both API manufacturer as well as drug product manufacturer.

	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."	
5.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm has submitted API verification studies performed by drug product manufacturer.
6.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	Firm has submitted COA of relevant batch of API from both API manufacturer as well as drug product manufacturer.
7.	Justification of specifications of drug substance specifies that the drug substance is developed as per in house specifications, justify since JP monograph is available for the applied drug product	The drug substance has been developed as per JP and Chinese specifications, however the limits of all tests as well as detailed specifications complies JP monograph as well.
8.	Submit COA of working standard of drug substance in section 3.2.S.5.	Firm has submitted COA of working standard.
9.	Submit complete stability study data of three batches of drug substance in section 3.2.S.7.3.	Firm has submitted complete stability data of API three batches as per zone IV-A conditions.
10.	Submit BMR of three stability batches.	Firm has submitted BMR of three stability batches.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

31.	Name, address of Applicant / Marketing Authorization Holder	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 25-08-2020 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** Firm has submitted copy of GMP certificate dated 11-11-2022 issued on the basis of inspection dated 11-10-2022.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial 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 14296 dated 13-06-2022

	Details of fee submitted	PKR 75,000/- Dated 20-05-2022
	The proposed proprietary name / brand name	**CEBACTUM 2gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., **Bulgaria:** Sulcef 1g/1g powder for solution for injection **Lithuania:** Sulcef 1g/1g powder for solution for injection **Slovakia:** Sulcef 2g powder for solution for injection
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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 their product against Cebac Injection of Bosch Pharm.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.		
API Lot No.	1091EJ81NE		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
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)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
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. SD20190876) issued by CFDA China is submitted by the firm. The certificate is valid till 21-04-2024. Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter of loan and memorandum of understanding with M/s Swiss Pharma for getting 10Kg loan of Cefoperazone sodium and sulbactam sodium.

		• Firm has submitted copy of invoice specifying import of 40Kg Cefoperazone sodium and sulbactam sodium by M/s Swiss Pharma. The invoice is cleared by AD (I&E) DRAP dated 11-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability 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:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the brand name of the applied product, since Cebactum injection is mentioned in few section while Parabactum Injection is mentioned in other sections.	Cebactum Injection is our proposed brand name while Parabactum is typographic mistake. The registered brand of the manufacturer is Cefbac injection and the attached stability data is of cefbac injection.
2.	Specify the exact source of drug substance including complete address, since the submitted document is in chinese language and are not readable.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.
3.	Submit complete module 3.2.S as per CTD guidance document since the submitted documents are not aligned as recommended in the guidance document.	Firm has submitted complete module 3.2.S as per the guidance document approved by Registration Board.
4.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of API and its analytical method from both API manufacturer as well as drug product manufacturer.
5.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm has submitted API verification studies performed by drug product manufacturer.

6.	Submit COA of the relevant batch of API used in the development for three stability batches in section 3.2.S.4.4.	Firm has submitted COA of relevant batch of API from both API manufacturer as well as drug product manufacturer.
7.	Justification of specifications of drug substance specifies that the drug substance is developed as per in house specifications, justify since JP monograph is available for the applied drug product	The drug substance has been developed as per JP and Chinese specifications, however the limits of all tests as well as detailed specifications complies JP monograph as well.
8.	Submit COA of working standard of drug substance in section 3.2.S.5.	Firm has submitted COA of working standard.
9.	Submit complete stability study data of three batches of drug substance in section 3.2.S.7.3.	Firm has submitted complete stability data of API three batches as per zone IV-A conditions.
10.	Submit BMR of three stability batches.	Firm has submitted BMR of three stability batches.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 3: M/s Bio-Labs(Pvt). Ltd.

The following case was referred to PEC from Assistant Director PR-I/EFD vide letter No. F.1-6/2019-PR-I (EFD) dated 28-02-2023.

32.	Name, address of Applicant / Marketing Authorization Holder	**M/s Bio-Labs(Pvt). Ltd Plot No. 145 Industrial Triangle Kahuta Road Islamabad**
	Name, address of Manufacturing site.	M/s Bio-Labs(Pvt). Ltd Plot No. 145 Industrial Triangle Kahuta Road Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional sections dated 24-03-2007 specifying Tablet (General) section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 3219 dated 03-02-2023
	Details of fee submitted	PKR 75,000/- Dated 18-01-2023
	The proposed proprietary name / brand name	**BIOXOVID 150/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each combo pack contains**: Each film coated tablet contains: Nirmatrelvir ……..150mg Each film coated tablet contains: Ritonavir ……..100mg
	Pharmaceutical form of applied drug	**Nirmatrelvir**: Blue colored, oblong shaped film coated Tablets **Ritonavir:** White colored, oblong shaped film coated Tablets.
	Pharmacotherapeutic Group of (API)	Nirmatrelvir: Oral Protease inhibitor Ritonavir: CYP3A Inhibitor and antiretroviral oral Protease Inhibitor drug

	Reference to Finished product specifications	Nirmatrelvir: Innovator Specifications Ritonavir: USP Specification
	Proposed Pack size	30's Each Blister contains : 4 Blue colored, film coated Nirmatrelvir tablets……..150mg 2 white, film coated Ritonavir tablets……100mg Packed in Alu-PVC foil enclosed with leaflet.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paxlovid 150 mg/100 mg film-coated tablets (MHRA granted its Conditional Marketing Authorisation)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Nirmatrelvir**: Zenji Pharmaceuticals (Suzhou) Ltd. No. 122, Xuqing Road, Xuguan Town, Suzhou, Jiangsu China. **Ritonavir**: Shanghai Desano Chemical Pharmaceutical Co. Ltd. No. 417 Binhai Road,Laogang Town, Pudong New Area, Shanghai, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Nirmatrelvir**: 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. **Ritonavir**: 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.
	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 their product against Jupitavir Tablet of Incepta Pharmaceutical Ltd. Firm has submitted results of pharmaceutical equivalence for their product against Jupitavir Tablet of Incepta Pharmaceutical Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	**Nirmatrelvir**: Zenji Pharmaceuticals (Suzhou) Ltd. No. 122, Xuqing Road, Xuguan Town, Suzhou, Jiangsu China. **Ritonavir**: Shanghai Desano Chemical Pharmaceutical Co. Ltd. No. 417 Binhai Road,Laogang Town, Pudong New Area, Shanghai, China		
API Lot No.	**Nirmatrelvir**: **Ritonavir**:		
Description of Pack (Container closure system)	Alu-PVC Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BXD-001	BXD-002	BXD-003
Batch Size	Nirmatrelvir: 400 Tab Ritonavir: 200 Tab	Nirmatrelvir: 400 Tab Ritonavir: 200 Tab	Nirmatrelvir: 400 Tab Ritonavir: 200 Tab
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	15-07-2022	15-07-2022	15-07-2022
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)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
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	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

- As per MHRA Public Assessment Report, the innovator product Paxlovid has been granted a Conditional Marketing Authorisation (CMA) instead of complete marketing authorization, Justify how this reference can be used as evidence of approval of reference regulatory authorities for safety and efficacy.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 for Nirmatrelvir drug substance 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 of verification of analytical procedure of Nirmatrelvir drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Further justify how the analysis of drug substance was performed without performing verification studies.
- Submit COA of the relevant batch of Nirmatrelvir API used in the development for three stability batches in section 3.2.S.4.4.
- Submit COA of reference standard actually used in the analysis of Nirmatrelvir drug substance.
- Nirmatrelvir contained in Paxlovid Tablet was granted Conditional Marketing Authorisation by MHRA on 31-12-2021, while your drug substance manufacturer has submitted stability study data of 3 batches of drug substance which were manufacturer in January 2020. Clarification is required in this regard.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 for Ritonavir drug substance 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 of verification of analytical procedure of Ritonavir drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Further justify how the analysis of drug substance was performed without performing verification studies.
- Submit COA of the relevant batch of Ritonavir API used in the development for three stability batches in section 3.2.S.4.4.
- Submit COA of reference standard actually used in the analysis of Ritonavir drug substance.
- The applied product is a co-blister, while the blistering step is not included in the process validation protocols. Justify how these protocols will truly validate the process for the applied product.
- Justify the adaptation of dissolution parameters (i.e. dissolution medium, type of apparatus, RPM and time) for the Nirmatrelvir drug product, further justify how this method would be discriminatory in nature to avoid batch to batch variations as required under the applicable ICH and FDA guidelines as well as the guidelines approved by Registration Board in its 293rd meeting.
- Justify the dissolution acceptance criteria for Nirmatrelvir Tablet i.e. NLT 75%(Q) in 120 minutes, while the drug product is an immediate release product.
- The analytical procedure of Nirmatrelvir defined by the drug substance manufacturer specify two different mobile phase with a gradient elution over the period of 36 minutes to quantify the active substance, while in drug product your analytical method specify only single mobile phase with isocratic system. Clarification is required in this regard.
- Specify the diluent / blank and placebo used in specificity test of Nirmatrelvir Tablet.
- Specify the exact concentration of each test solution in linearity and range test, accuracy and recovery test of Nirmatrelvir Tablet.
- In robustness test, your have mentioned change in temperature, change in pH and change in sonication time. Specify the exact change in all these parameters and also specify whether this change was in pH, temperature of sample solutions, mobile phase, buffer or which particular parameter. Further justify the performance of this test as per ICH guidelines.
- Your sample and standard solution concentration is 0.1mg/ml, while in detection limit and quantitation limit test your results are NMT 3 and NMT 10 which does not specify any unit, furthermore justify the performance of this test as per ICH guidelines including interpretation of results of this test.

- The calculation formula for assay test mentioned in drug product specifications is different than the formula used in calculation of results of linearity, accuracy & recovery test etc. Clarification is required in this regard.
- The applied product is a co-blistered product while you have submitted seprate batch release certificate for both tablets. Clarification is required whether both tablets will be manufactured with different batch numbers and will be released separately or will be manufactured under a single batch number along with common batch release certificate.
- Provide details of the finally blistered and packed product which were kept on stability studies including picture of each blister and count of number of tablets in each blister and total number of blisters in a pack.
- Evidence of co-blister machine which is required for blistering of the applied product.
- Provide data of comparative dissolution profile of the applied product against the innovator / reference product.
- Submit BMR of three stability batches.
- 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case No. 4: M/s Welmark Pharmaceuticals.

The following case was referred to PEC from Assistant Director PR-I/EFD vide letter No. F.1-6/2019-PR-I (EFD) dated 29-12-2022.

33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals Plot # 122 Block-B, Phase-V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot # 122 Block-B, Phase-V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 23-11-2021 issued based on inspection dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 23-11-2021 issued based on inspection dated 11-11-2021. The certificate specifies Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 6127 dated 07-03-2022
	Details of fee submitted	PKR 75,000/- Dated 24-02-2022
	The proposed proprietary name / brand name	**ZILTAN 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 80mg

	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	White to off white colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	4 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, 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 drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet 80mg manufactured by Takeda Ireland Ltd.. Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 80mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	19AK00006		
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.	T025	T026	T027
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	22-03-2021	24-03-2021	25-03-2021
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)	Last PSI was conducted for Dapzin Tablet, for which the inspection was conducted on 27-04-2021 and the report was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 16-052-2019 specifying 0.540Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The label claim of innovator's product specifies that each tablet contains 80mg of Azilsartan medoxomil as potassium salt, while your label claim specifies that each tablet contains 80mg of Azilsartan medoxomil potassium. Revise your	That was a typographic mistake that we have corrected the label claim that is Each tablet contains: Azilsartan Medoxomil as potassium …..80mg (Innovators spec) Firm has **not** submitted any fee

	label claim as per the innovator's product.	
2.	Analytical method for assay testing of drug substance specifies a gradient elution system with a run time upto 40 minutes, while the drug product manufacturer has specified isocratic elution with run time upto 10 minutes. Clarification is required how drug product manufacturer can use a different analytical method of the drug substance from that recommended by the drug substance manufacturer.	We have used gradient method of analysis for drug substance provided by the drug substances manufacturer with a run time upto 40 minutes. Although we have used isocratic method of analysis for drug product with run time of upto 10 minutes.
3.	Justify the performance of specificity test under verification studies of drug substance in the light of ICH guidelines, since you have specified that the test was performed by spiking blank sample with test sample and excipients. Justify what was the blank and test sample and how excipients were spiked in drug substance testing.	We have performed specificity test under verification studies of drug substance in the light of ICH guidelines. We run blank sample and standard dilution sample dilution and impurity standard but excipients are spiked during product method validation We use diluent as blank sample
4.	Specify the exact concentration of each solution studied at 80%, 100% and 120% in accuracy and recovery studies. Further specify the formula used to calculate accuracy and recovery results.	The exact concentration of 80% is 0.2mg/ml, 100% is 0.25mg/ml and 120 % is 0.3mg/ml. Accuracy should be assessed using a minimum of 9 determinations over a minimum of 3 concentration levels covering the specified range (e.g., 3 concentrations/3 replicates each of the total analytical procedure), Accuracy should be reported as percent recovery by the assay of known added amount of analyte in the sample or as the difference between the mean and the accepted true value together with the confidence intervals.
5.	Analysis of the drug substance lot number 19AK00006 was performed on 24-12-2020 while API verification studies were performed on 26-12-2020. Justify how the testing of drug substance was carried prior to verification studies.	We have retested the drug substance and verification studied according to ICH guideline lot number 19AK00006 was performed on March 2020. Again we have retested and reverification study performed. Intra- day precision was performed on next day
6.	The COA of API lot number 19AK00006 specifies the retest date as March 2020 while you have performed API testing on 24-12-2020 (almost 9 months after the API retest period). Justify how you have used an API which have exceeded its limit of use as specified by its manufacturer.	We have retested the drug substance lot number 19AK00006 was performed on March 2020. According to API stability study provided by manufacturer. This salt is stable for 2 year on basis of stability study. We have again retested the drug substance in December 2020 before manufacturing trial batches of Ziltan 40 and 80 mg tablet
7.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 10 minutes in both of these medias.	We have reviewed comparative dissolution profile. Azilsartan is unstable in 0.1 HCL solution and 4.5 acetate buffer the result in 0.1 N HCL solution 32 to 35% of both Welmark and innovator product and result were found 35 to 40% in 4.5 acetate buffer in 45 minutes

8.	Justify the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.	FDA has approved up to 45 minutes for dissolution but our product is dissolved before 30 min. We have reviewed time limit for dissolution. Our specification is the valu of (Q) NLT 75% in 30 minutes.
9.	Your sample and standard solution concentration is 0.25mg/ml, while in detection limit and quantitation limit test your results are 90% - 110% which does not specify result of this test, furthermore justify the performance of this test as per ICH guidelines including interpretation of results of this test.	The limit of detection (LOD) and limit of quantitation (LOQ) is 0.0155% and 0.0062% respectively
10.	Justify why the peak for fumaric acid is not observed during the stability studies since fumaric acid is included in the formulation.	We have used fumaric acid in very small quantity in formulation and very small peak observed in 3 minutes
11.	Azilsartan base is identified as an impurity in azilsartan medoxomil and the peak for azilsartan is also observed in HPLC analysis. Clarify why azilsartan base is not observed in any analysis during stability studies.	Azilsaratan base impurity is shown in our chromatogram and it lies with in the limits.
12.	Justify the dispensing of 85.360mg API in each tablet since each tablet is claimed to contain 80mg Azilsartan medoxomil.	Azilsartan Medoxomil as potassium …..80mg (Innovators spec) documents of formulation and calculation of potassium factor are submitted.

Decision: Deferred for following submissions:

- **Submission of full fee of registration for pre-approval change in label claim/ master formula as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Scientific justification for adapting isocratic elution with run time upto 10 minutes for analysis of drug substance, since the drug substance manufacturer has specified a gradient elution system with a run time upto 40 minutes.**
- **Justify the analysis of drug substance prior to the performance of verification studies of analytical method of drug substance.**
- **Scientific justification for the use of an API which have exceeded its limit of use as specified by its manufacturer, since you have used API lot number 19AK00006 on 24-12-2020, while the drug substance manufacturer has specified the retest date as March 2020.**
- **Scientific justification for the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
34.	M/s Welmark Pharmaceuticals Plot # 122 Block-B, Phase-V, Industrial Estate Hattar.	ZILTAN 40mg Tablet Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 40mg (Angiotensin Receptor Blocker) In-house specifications	Form 5-D Dy No. 16469 07-03-2019 PKR. 20,000/- (06-03-2019) + PKR 55,000/- (08-02-2022) As per SRO	Approved by USFDA Firm has submitted copy of GMP certificate dated 23-11-2021 issued based on inspection dated 11-11-2021.

Remarks of Evaluator:

- The firm has submitted stability study data along with required documents as per checklist approved in 293rd meeting of Registration Board. Details of submitted data are as under:

(Dy.# 3623 dated 08-02-2022)

STABILITY STUDY DATA			
Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.	19AK00006		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.	T022	T023	T024
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	15-03-2021	16-03-2021	17-03-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Dapzin Tablet, for which the inspection was conducted on 27-04-2021 and the report was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 16-052-2019 specifying 0.540Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study

8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 40mg.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail report is not submitted by the firm.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for both stability chambers for accelerated as well as real time stability studies.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The COA of API lot number 19AK00006 specifies the retest date as March 2020 while you have performed API testing on 24-12-2020 (almost 9 months after the API retest period). Justify how you have used an API which have exceeded its limit of use as specified by its manufacturer.	We have retested the drug substance and verification studied according to ICH guideline lot number 19AK00006 was performed on March 2020. Again we have retested and reverification study performed. Intra- day precision was performed on next day
2.	Provide comparative dissolution profile of the applied product against the innovator's product.	Comparative dissolution profile of the applied drug product against the innovators product is submitted.
3.	Justify the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.	FDA has approved up to 45 minutes for dissolution but our product is dissolved before 30 min. We have reviewed time limit for dissolution. Our specification is the valu of (Q) NLT 75% in 30 minutes
4.	Justify why the peak for fumaric acid is not observed during the stability studies since fumaric acid is included in the formulation.	We have used fumaric acid in very small quantity in formulation and very small peak observed in 3 minutes
5.	Azilsartan base is identified as an impurity in azilsartan medoxomil and the peak for azilsartan is also observed in HPLC analysis. Clarify why azilsartan base is not observed in any analysis during stability studies.	Azilsaratan base impurity is shown in our chromatogram and it lies with in the limits
6.	Submit BMR of three stability batches.	Firm has submitted BMR of three stability batches.
7.	Provide audit trail report on product testing as compliance Record of HPLC software 21CFR compliance.	Audit trail report is not submitted by the firm.

Decision: Deferred for following submissions:

- **Submission of full fee of registration for pre-approval change in label claim/ master formula as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Scientific justification for adapting isocratic elution with run time upto 10 minutes for analysis of drug substance, since the drug substance manufacturer has specified a gradient elution system with a run time upto 40 minutes.**

- **Justify the analysis of drug substance prior to the performance of verification studies of analytical method of drug substance.**
- **Scientific justification for the use of an API which have exceeded its limit of use as specified by its manufacturer, since you have used API lot number 19AK00006 on 24-12-2020, while the drug substance manufacturer has specified the retest date as March 2020.**
- **Scientific justification for the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.**

Case No. 02 Registration applications of CTD cases

a. Deferred cases of local manufacturing

35.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 29-10-2020 is submitted.
	GMP status of the firm	**Genetics Pharmaceuticals:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 29-03-2019. **Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000783 of M/s Stallion Pharma Islamabad dated 08-02-2016 specifying dry powder injection Vial (carbapenem) 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. 13638: 20-05-2021
	Details of fee submitted	PKR 50,000/-: 30-11-2020
	The proposed proprietary name / brand name	**MEROTOL 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 500mg Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
API Lot No.	1705205135 1705205096 1705203623
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.	T7003	T7004	T7005
Batch Size	7800 vials	7800 vials	7570 vials
Manufacturing Date	09-2017	10-2017	11-2017
Date of Initiation	25-09-2017	13-11-2017	16-11-2017
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 response submitted by the firm
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. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
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 20th May 2021.	Firm has submitted copy of fee challan dated 28-10-2021 for 25,000/- vide slip number 08343787921
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of analytical method of drug substance from the drug product manufacturer. The analytical method is issued on 20-07-2021.
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.	Firm has submitted report of verification studies of the analytical method of drug substance. However, the verification studies were conducted on 21-01-2021 while the analytical method of drug substance was issued by the drug product manufacturer on 20-07-2021.

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. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".	Firm has submitted COA of the drug substance generated by drug product manufacturer only, while the COA of drug substance manufacturer is not submitted.
Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug substance and drug product.	Firm has submitted COA of working standard from drug substance manufacturer which has been standardized against USP reference standard. However drug product manufacturer is using working standard of meropenem Batch No. SI/MPM/00060120 manufactured by M/s Sterile India.
Justify the master formulation containing 570mg of meropenem trihydrate for manufacturing of 500mg meropenem for injection, since the drug substance contains meropenem blended with 15.10 to 16.50% w/w of sodium carbonate.	Firm has submitted calculation to justify the filled weight. As per calculations submitted by the firm the weight 570mg per vial is calculated on theoretical basis considering that the drug substance has 100% assay, while the actual dispensing is to be made on the basis of actual % assay of the meropenem.
Justify the use of 5% overage in the formulation, since the justification submitted in this regard is not supported by any guidelines.	We hereby justify that in development stage we added 5% extra meropenem sterile powder for injection in initial batches. After completion of stability study degradation is no more than 2 – 3% within the limit assay range is 90 – 120% so no more 5% meropenem sterile powder for injection is added.
Submit results of compatibility studies in section 3.2.P.2.6.	Firm has submitted result of compatibility studies of the drug product with WFI.
Justify how the time and temperature of sterilization cycle is directly selected without any protocols for its validation.	Firm has submitted summary report of autoclave machine re qualification instead of providing justification.
Provide detailed method of sample stock solution preparation instead of mentioning the general statement "Constitute a container of Meropenem for Injection with a volume of water, corresponding to the quantity of solvent specified in the labelling".	Firm has not submitted complete method of analysis of the drug product in which the method of sample solution preparation is explained.
Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm has submitted that we are using potency of working standard as percentage. USP taking the potency in mg/mg which is converted into percentage by multiplying this ratio with 100. Firm has submitted calculation to justify that their formula is equivalent to USP. However, the USP formula used by the firm is different from that specified in USP.
Analytical method verification studies have not been conducted and evaluated in the light of USP general chapters and ICH guidelines.	Firm has submitted verification studies of the analytical method dated 21-01-2021, while the analytical method of the drug product was revised and updated on 12-07-2021.
Justify why the drug product specifications does not contain the test for sodium contents as recommended by USP.	In Meropenem trihydrate injection label claim is as meropenem while trihydrate and sodium considered as impurity. We are verifying the meropenem by HPLC and due to unavailability of the atomic absorption we were verifying the

	sodium content by titration method. Moreover, for verification purpose, we analysed sodium content from PCSI and Citi Pharma with atomic absorption. And now we have atomic absorption in our facility and we have changed our SOP accordingly and now we are conducting each and every analysis of sodium content in our facility as per USP monograph.
Justify the test of accuracy in analytical method validation without specifying the concentrations of the solution which are analysed for accuracy. Further justify the use of solutions having low, medium, and high concentration of sample without specifying their exact concentration. Such words are not recommended by any scientific guidelines.	Firm has submitted that we had performed the accuracy by making a concentration of standard preparation and three concentrations. The concentrations used by the firm for accuracy test is 0.16mg/ml, 0.20mg/ml and 0.24mg/ml. As per the analytical method the standard solution concentration is 0.11mg/ml and the concentration used by the firm to study accuracy does not include the said concentration.
Linearity and range have been studied from 70% to 120% of the solution wherein the area under curve for 100% solution was 4691449 while in accuracy studies in the same method none of the solution (either low, medium or high concentration) achieved such area although the concentration of the solution is expected to be the same. Justification is required in this regard.	Two different samples were prepared for linearity and accuracy parameter of analytical method verification, for linearity parameter from the first dilution 6 further second dilutions 70%, 80%, 90%, 100%, 110% and 120% were prepared while in accuracy 3 further second dilutions low, medium and high were prepared. Because the weights of the sample are different in linearity and accuracy parameters that's why the area achieved is different for both parameters.
In linearity studies the area under curve for 100% solution was 4691449, while in stability studies the area under curve of the sample solution having exactly same concentration is reported to be 11769485. Justification is required in this regard how such huge difference in area under the curve can exist in the analysis and how this method can be considered reliable and verified.	In linearity the sample solution preparation is different from the sample preparation of finished product. In linearity a concentration of standard taken to prepare first dilution then make second dilution by taking 7ml, 8ml, 9ml, 10ml, 11ml, 12ml from the first dilution, second dilution of 10ml is considered as 100% concentration while in finished good the dilution contain 100mg of sample that's why area under curve for 100% solution is different from the area of 100mg in finished product.
The analytical method verification studies have been conducted in January 2021 while the batches were manufactured in 2017. Justification is required in this regard.	In 2017, we had completed analytical method verification by performing three parameters which are linearity, system suitability and specificity while when we submit the CTD dossier we came to know the DRAP requirement of accuracy and repeatability, then we had complete the analytical method verification by performing five parameters which are linearity, system suitability, specificity accuracy and repeatability.
Justify the limit of sodium content in the in house generated COA of drug substance, in which limit of sodium content is taken as 6.0% to 9.3% and the drug substance was passed on the basis of results of 9.12%, while the drug substance manufacturer specifies the limit of sodium content as 6.56% to 7.20%. As per the submitted results of sodium content in meropenem injection by CITI Pharma, the results of % sodium content is 7.867%, while USP specifies the acceptance criteria to be 80%–120% of the labeled amount of sodium. Justify how your results complies USP specifications keeping in view the labelled amount of sodium in your product.	In past we were doing sodium content analysis by titration method (due to unavailability of AAS) the result was 9.12% limit of sodium content is 6.0% - 9.3% while the drug substance manufacturer specifies the sodium content as 6.65 to 7.20%. Now we are doing sodium content with AAS according to USP. Firm has not submitted any justification

Justify the use of commercial lot of meropenem for injection as working standard since USP recommends that reference standard should be pure meropenem trihydrate.	The assay of meropenem trihydrate USP reference standard lot# J0K434, is 87.3% meropenem. Similarly by comparing with reference standard we prepare our meropenem trihydrate working standard in which 82.12% is meropenem present. Actually the material used in USP Reference standard and the working standard is the same as meropenem trihydrate because the product label claim is meropenem, therefore we have to calculate the assay against the purity of material as meropenem which is 87.3% in USP Reference standard and 82.12% in working standard.
Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has not submitted details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Further documents confirming import of these relevant batches are also required.
Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point, since the submitted chromatograms and analytical reports are without any proper sequence.	Firm has not yet submitted stability study data in proper sequence with COA for each time point, raw data sheets and chromatograms. Raw data sheets are not submitted. Further the calculation formula used for the calculation of assay result is also different from USP as well as the method of sample and standard solution preparation.
Provide Reference of previous approval of applications with stability study data of the firm (if any)	No response submitted by the firm
Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No response submitted by the firm
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	No response submitted by the firm

Decision of 316th meeting of Registration Board:

Deferred for following:

- Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.
- Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.
- Scientific justification for use of 5% overage in the formulation.
- Submission of complete protocols of process validation studies of the drug product.
- Submission of detailed method of analysis of the drug product with details of sample solution preparation.
- Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.
- Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.	Firm has submitted COA of relevant batch of drug substance generated by drug substance manufacturer.

2.	Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.	This firm has submitted that the assay of Meropenem Trihydrate USP reference standard lot # J0k434 is 87.3%. Therefore, we used sterile India material as working Standard having potency 82.02% by using standardization procedure with USP reference standard. Material used for batch manufacturing is from Aurobindo China and working standard prepared is of Sterile India having Potency 82.02% COA's for Reference standard & working standard along with standardization procedure is submitted by the firm.
3.	Scientific justification for use of 5% overage in the formulation.	Firm has submitted that an overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
4.	Submission of complete protocols of process validation studies of the drug product.	Firm has submitted general protocols for process validation. **Firm has not submitted specific protocols for the process validation of applied product.**
5.	Submission of detailed method of analysis of the drug product with details of sample solution preparation.	Firm has submitted detailed method of analysis of the drug product, **However in the submitted method, sample solution preparation method is still not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions.** Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
6.	Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.	Firm has submitted that they are using the potency of working standard as percentage. USP taking the Potency into mg/mg which is covered into percentage multiplying the ratio with 100 so there is no difference between the USP formula & our standard operating formula further more we have amended our SOP with respect to the formula given in USP. **However, the newly used calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard. The new formula is also not exactly as per USP monograph.**
7.	Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product	Firm has now added sodium content test in their specifications. Firm has also submitted fee 7,500/- vide slip number 212267176 dated 20-05-2022.

	specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	**However, no data regarding the sodium content testing during stability studies is provided.**
8.	Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.	Firm has not justified the previous validation reports, instead the firm has submitted new report in which the analysis is carried out on July 2022. The new report was performed in line with ICH recommendations.
9.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted data in section 3.2.P.8.3. The evaluation os submitted data is as under:

Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
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. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
Documents for the procurement of API with approval from DRAP (in case of import).	**1705205135, 1705205096:** Firm has submitted copy of commercial invoice cleared dated 19-10-2017 specifying import of 20Kg meropenem for lot number 1705205135, 1705205096. The invoice is cleared by AD (I&E) DRAP. **1705203623:** Firm has submitted copy of commercial invoice cleared dated 12-09-2017 specifying import of 15Kg meropenem for lot number 1705203623. The invoice is cleared by AD (I&E) DRAP.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of product testing including HPLC chromatogram and raw data sheets
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for stability chambers for accelerated and real time stability study.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.
- Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
- Submission of specific protocols for the process validation of applied product.
- Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
- Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.	An overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
2.	Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.	Capacity assessment report is not yet received.
3.	Submission of specific protocols for the process validation of applied product.	Firm has submitted process validation protocols
4.	Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.	Firm has submitted revised testing method and specifications.
5.	Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.	Firm has submitted revised testing method and specifications

Evaluation by PEC[3]:

Registration Board in its 323rd meeting was apprised that the applied formulation has already been approved in 312th meeting of Registration Board for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, wherein following submission had also been made by the firm and above mentioned points have been addressed and responded:

- Evidence for purchase of atomic absorption spectrophotometer in the form of purchase order dated 14-06-2021, deliver challan dated 19-06-2021 & invoice No. 06/3029 dated 18-06-2021.
- Installation and operational qualification reports of atomic absorption spectrophotometer.
- Analysis report of Sodium Content in Mopen (Meropenem) Injection by M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.

The applied formulation of contract manufacturer is already previously approved by the Registration Board. The details of already approved product of same formulation of the contract manufacturer is provided below:

Applicant firm	M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25 Sector 20, Korangi Industrial Area Karachi
Manufacturer firm	M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore
Brand Name	ASPINEM 500 mg Injection
Batch No. of drug product	T7003,T7004,T7005
Case No.	747
Registration Board meeting	323rd meeting of DRB

Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**

36.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 29-10-2020 is submitted
	GMP status of the firm	**Genetics Pharmaceuticals:** Firm has submitted copy of GMP certificate issued on the basis of inspection dated 29-03-2019. **Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000783 of M/s Stallion Pharma Islamabad dated 08-02-2016 specifying dry powder injection Vial (carbapenem) 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. 16253: 11-06-2021
	Details of fee submitted	PKR 50,000/-: 30-11-2020
	The proposed proprietary name / brand name	**MEROTOL 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1g (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals

	Name and address of API manufacturer.	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 1g Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
API Lot No.	1705205135 1705205096 1705203623
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.	U7003	U7004	U7005
Batch Size	3900 vials	7600 vials	3780 vials
Manufacturing Date	09-2017	10-2017	11-2017
Date of Initiation	04-10-2017	14-11-2017	17-11-2017
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 response submitted by the firm
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. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not 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

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
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 11th June 2021.	Firm has submitted fee challan dated 28-12-2021 for 25,000/- vide slip number 16540367178
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of analytical method of drug substance from the drug product manufacturer. The analytical method is issued on 20-07-2021.
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.	Firm has submitted report of verification studies of the analytical method of drug substance. However, the verification studies were conducted on 21-01-2021 while the analytical method of drug substance was issued by the drug product manufacturer on 20-07-2021.
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	Firm has submitted COA of the drug substance generated by drug product manufacturer only,

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. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".	while the COA of drug substance manufacturer is not submitted.
Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug substance and drug product.	Firm has submitted COA of working standard from drug substance manufacturer which has been standardized against USP reference standard. However drug product manufacturer is using working standard of meropenem Batch No. SI/MPM/00060120 manufactured by M/s Sterile India.
Justify the master formulation containing 1140mg of meropenem trihydrate for manufacturing of 1g meropenem for injection, since the drug substance contains meropenem blended with 15.10 to 16.50% w/w of sodium carbonate.	Firm has submitted calculation to justify the filled weight. As per calculations submitted by the firm the weight 1140mg per vial is calculated on theoretical basis considering that the drug substance has 100% assay, while the actual dispensing is to be made on the basis of actual % assay of the meropenem.
Justify the use of 5% overage in the formulation, since the justification submitted in this regard is not supported by any guidelines.	We hereby justify that in development stage we added 5% extra meropenem sterile powder for injection in initial batches. After completion of stability study degradation is no more than 2 – 3% within the limit assay range is 90 – 120% so no more 5% meropenem sterile powder for injection is added.
Submit results of compatibility studies in section 3.2.P.2.6.	Firm has submitted result of compatibility studies of the drug product with WFI.
Justify how the time and temperature of sterilization cycle is directly selected without any protocols for its validation.	Firm has submitted summary report of autoclave machine re qualification instead of providing justification.
Provide detailed method of sample stock solution preparation instead of mentioning the general statement "Constitute a container of Meropenem for Injection with a volume of water, corresponding to the quantity of solvent specified in the labelling".	Firm has not submitted complete method of analysis of the drug product in which the method of sample solution preparation is explained.
Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm has submitted that we are using potency of working standard as percentage. USP taking the potency in mg/mg which is converted into percentage by multiplying this ratio with 100. Firm has submitted calculation to justify that their formula is equivalent to USP. However, the USP formula used by the firm is different from that specified in USP.
Analytical method verification studies have not been conducted and evaluated in the light of USP general chapters and ICH guidelines.	Firm has submitted verification studies of the analytical method dated 21-01-2021, while the analytical method of the drug product was revised and updated on 12-07-2021.
Justify why the drug product specifications does not contain the test for sodium contents as recommended by USP.	In Meropenem trihydrate injection label claim is as meropenem while trihydrate and sodium considered as impurity. We are verifying the meropenem by HPLC and due to unavailability of the atomic absorption we were verifying the sodium content by titration method. Moreover, for verification purpose, we analysed sodium content from PCSI and Citi Pharma with atomic

	absorption. And now we have atomic absorption in our facility and we have changed our SOP accordingly and now we are conducting each and every analysis of sodium content in our facility as per USP monograph.
Justify the test of accuracy in analytical method validation without specifying the concentrations of the solution which are analysed for accuracy. Further justify the use of solutions having low, medium, and high concentration of sample without specifying their exact concentration. Such words are not recommended by any scientific guidelines.	Firm has submitted that we had performed the accuracy by making a concentration of standard preparation and three concentrations. The concentrations used by the firm for accuracy test is 0.16mg/ml, 0.20mg/ml and 0.24mg/ml. As per the analytical method the standard solution concentration is 0.11mg/ml and the concentration used by the firm to study accuracy does not include the said concentration.
Linearity and range have been studied from 70% to 120% of the solution wherein the area under curve for 100% solution was 4691449 while in accuracy studies in the same method none of the solution (either low, medium or high concentration) achieved such area although the concentration of the solution is expected to be the same. Justification is required in this regard.	Two different samples were prepared for linearity and accuracy parameter of analytical method verification, for linearity parameter from the first dilution 6 further second dilutions 70%, 80%, 90%, 100%, 110% and 120% were prepared while in accuracy 3 further second dilutions low, medium and high were prepared. Because the weights of the sample are different in linearity and accuracy parameters that's why the area achieved is different for both parameters.
In linearity studies the area under curve for 100% solution was 4691449, while in stability studies the area under curve of the sample solution having exactly same concentration is reported to be 11769485. Justification is required in this regard how such huge difference in area under the curve can exist in the analysis and how this method can be considered reliable and verified.	In linearity the sample solution preparation is different from the sample preparation of finished product. In linearity a concentration of standard taken to prepare first dilution then make second dilution by taking 7ml, 8ml, 9ml, 10ml, 11ml, 12ml from the first dilution, second dilution of 10ml is considered as 100% concentration while in finished good the dilution contain 100mg of sample that's why area under curve for 100% solution is different from the area of 100mg in finished product.
The analytical method verification studies have been conducted in January 2021 while the batches were manufactured in 2017. Justification is required in this regard.	In 2017, we had completed analytical method verification by performing three parameters which are linearity, system suitability and specificity while when we submit the CTD dossier we came to know the DRAP requirement of accuracy and repeatability, then we had complete the analytical method verification by performing five parameters which are linearity, system suitability, specificity accuracy and repeatability.
Justify the limit of sodium content in the in house generated COA of drug substance, in which limit of sodium content is taken as 6.0% to 9.3% and the drug substance was passed on the basis of results of 9.12%, while the drug substance manufacturer specifies the limit of sodium content as 6.56% to 7.20%.	In past we were doing sodium content analysis by titration method (due to unavailability of AAS) the result was 9.12% limit of sodium content is 6.0% - 9.3% while the drug substance manufacturer specifies the sodium content as 6.65 to 7.20%. Now we are doing sodium content with AAS according to USP.
As per the submitted results of sodium content in meropenem injection by CITI Pharma, the results of % sodium content is 7.867%, while USP specifies the acceptance criteria to be 80%–120% of the labeled amount of sodium. Justify how your results complies USP specifications keeping in view the labelled amount of sodium in your product.	Firm has not submitted any justification
Justify the use of commercial lot of meropenem for injection (batch number SI/MPM/00060120) manufactured by sterile India as working standard	The assay of meropenem trihydrate USP reference standard lot# J0K434, is 87.3% meropenem. Similarly by comparing with reference standard we

since USP recommends that reference standard should be pure meropenem trihydrate.	prepare our meropenem trihydrate working standard in which 82.12% is meropenem present. Actually the material used in USP Reference standard and the working standard is the same as meropenem trihydrate because the product label claim is meropenem, therefore we have to calculate the assay against the purity of material as meropenem which is 87.3% in USP Reference standard and 82.12% in working standard.
Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has not submitted details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Further documents confirming import of these relevant batches are also required.
Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point, since the submitted chromatograms and analytical reports are without any proper sequence.	Firm has not yet submitted stability study data in proper sequence with COA for each time point, raw data sheets and chromatograms. Raw data sheets are not submitted. Further the calculation formula used for the calculation of assay result is also different from USP as well as the method of sample and standard solution preparation.
Provide Reference of previous approval of applications with stability study data of the firm (if any)	No response submitted by the firm
Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No response submitted by the firm
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	No response submitted by the firm

Decision of 316th meeting of Registration Board:

Deferred for following:

- Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.
- Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.
- Scientific justification for use of 5% overage in the formulation.
- Submission of complete protocols of process validation studies of the drug product.
- Submission of detailed method of analysis of the drug product with details of sample solution preparation.
- Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.
- Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.	Firm has submitted COA of relevant batch of drug substance generated by drug substance manufacturer.
2.	Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.	This firm has submitted that the assay of Meropenem Trihydrate USP reference standard lot # J0k434 is 87.3%. Therefore, we used sterile India material as working Standard having

		potency 82.02% by using standardization procedure with USP reference standard. Material used for batch manufacturing is from Aurobindo China and working standard prepared is of Sterile India having Potency 82.02% COA's for Reference standard & working standard along with standardization procedure is submitted by the firm.
3.	Scientific justification for use of 5% overage in the formulation.	Firm has submitted that an overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
4.	Submission of complete protocols of process validation studies of the drug product.	Firm has submitted general protocols for process validation. **Firm has not submitted specific protocols for the process validation of applied product.**
5.	Submission of detailed method of analysis of the drug product with details of sample solution preparation.	Firm has submitted detailed method of analysis of the drug product, **However in the submitted method, sample solution preparation method is still not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions.** Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
6.	Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.	Firm has submitted that they are using the potency of working standard as percentage. USP taking the Potency into mg/mg which is covered into percentage multiplying the ratio with 100 so there is no difference between the USP formula & our standard operating formula further more we have amended our SOP with respect to the formula given in USP. **However, the newly used calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard. The new formula is also not exactly as per USP monograph.**
7.	Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has now added sodium content test in their specifications. Firm has also submitted fee 7,500/- vide slip number 45752149528 dated 20-05-2022. **However, no data regarding the sodium content testing during stability studies is provided.**
8.	Scientific justification for the analytical method verification studies of the drug	Firm has not justified the previous validation reports, instead the firm has submitted new report in which the analysis is carried out on July 2022.

	product which is not performed as per ICH guidelines.	The new report was performed in line with ICH recommendations.
9.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted data in section 3.2.P.8.3. The evaluation os submitted data is as under:

Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
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. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
Documents for the procurement of API with approval from DRAP (in case of import).	**1705205135, 1705205096:** Firm has submitted copy of commercial invoice cleared dated 19-10-2017 specifying import of 20Kg meropenem for lot number 1705205135, 1705205096. The invoice is cleared by AD (I&E) DRAP. **1705203623:** Firm has submitted copy of commercial invoice cleared dated 12-09-2017 specifying import of 15Kg meropenem for lot number 1705203623. The invoice is cleared by AD (I&E) DRAP.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of product testing including HPLC chromatogram and raw data sheets
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for stability chambers for accelerated and real time stability study.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.
- Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
- Submission of specific protocols for the process validation of applied product.
- Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
- Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.	An overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to

		deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
2.	Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.	Capacity assessment report is not yet received.
3.	Submission of specific protocols for the process validation of applied product.	Firm has submitted process validation protocols
4.	Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.	Firm has submitted revised testing method and specifications.
5.	Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.	Firm has submitted revised testing method and specifications

Evaluation by PEC[3]:

Registration Board in its 323rd meeting was apprised that the applied formulation has already been approved in 312th meeting of Registration Board for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, wherein following submission had also been made by the firm and above mentioned points have been addressed and responded:

- Evidence for purchase of atomic absorption spectrophotometer in the form of purchase order dated 14-06-2021, deliver challan dated 19-06-2021 & invoice No. 06/3029 dated 18-06-2021.
- Installation and operational qualification reports of atomic absorption spectrophotometer.
- Analysis report of Sodium Content in Mopen (Meropenem) Injection by M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.

The applied formulation of contract manufacturer is already previously approved by the Registration Board. The details of already approved product of same formulation of the contract manufacturer is provided below:

Applicant firm	M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25 Sector 20, Korangi Industrial Area Karachi
Manufacturer firm	M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore
Brand Name	ASPINEM 1g Injection
Batch No. of drug product	U7003, U7004, U7005
Case No.	748
Registration Board meeting	323rd meeting of DRB

Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**

37.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26123 Dated 21-09-2021
	Details of fee submitted	PKR 30,000/- Dated 06-09-2021
	The proposed proprietary name / brand name	Fitbit PFS 20mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml of pre-filled syringe contains: Sodium hyaluronate……20mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anti-Inflammatory, Anti-arthritis
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	1's, 2's, 5's, 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	HYALGAN Injection 20mg/2ml by Fidia Farmaceutici S.p.A (AIFA Approved)
	For generic drugs (me-too status)	HYALGAN Injection Manufacture by *Fidia Farmaceutici S.p.A* Imported by: Liakat Pharma, Karachi Marketed by: Matrix Pharma Karachi DRAP Registration no. 031340
	GMP status of the Finished product manufacturer	The firm has submitted copy of GMP certificate based on inspection conducted on 09-11-2020. The firm has provided Biotech (Pre-filled syringe) section.
	Name and address of API manufacturer.	**Name:** M/s Contipro a.s., **Address:** Dolni Dobrouc 401 561 02 Dolni Dobrouc Czech Republic.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of sodium hyaluronate is not present in any Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of drug substance	Stability study conditions: Long term: 5°C ± 3°C for 36 months Accelerated: 25°C ± 2°C/65% ± 5%RH for 6 months Batches: (071114, 111207, N120815)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the reference product HYALGAN PFS Injection 20mg/2ml (Batch # D01240) of Matrix Pharma, Karachi by performing quality tests (Identification, Endotoxin test, Assay. pH). CDP is not required.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, Robustness, accuracy, precision (Repeatability), specificity.

STABILITY STUDY DATA

Manufacturer of API	**Name:** M/s Contipro a.s. **Address:** Dolni Dobrouc 401 561 02 Dolni Dobrouc Czech Republic.		
API Lot No.	SH-200129-F3		
Description of Pack (Container closure system)	Sterile prefilled syringe with Luer Lock System (Rigid cap), highly resistant borosilicate tubing glass (Type I) (1's, 2's ,5's,10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: Initial, 3, 6 (Months) Real time: Initial, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	500 PFS	500 PFS	500 PFS
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	01-01-2021	01-01-2021	01-01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to onsite inspection report of their product DASCOT 30mg & 60mg Tablet which was

		conducted on 26-01-2018, and was presented in 278th meeting of Registration Board. Following was reported in the report: • The HPLC software is 21CFR Compliant. • Audit trail reports were available and physically checked. The firm has data loggers for recording of temperature and humidity.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. sukls72897/2019 issued by Ministerstvo spravedlnosti CR Ministry of Justice of the Czech Republic. Issue & Valid Upto Dt: 15-07-2019 – 15-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice specifying import of 0.15 kg of sodium hyaluronate attested by Assistant Director (I & E) dated 08-11-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) was submitted.

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Submit valid copy of GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin.	Copy of GMP certificate (No. sukls72897/2019) issued by Ministerstvo spravedlnosti CR Ministry of Justice of the Czech Republic has been submitted. Issue & Valid Upto Dt: 15-07-2019 – 15-07-2022.
2.	Confirmation of manufacturing facility / section for the applied formulation.	
3.	Copies of the drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	The firm has submitted copies of the Drug substance specifications and analytical procedures for drug substance by drug product manufacturer.
4.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification protocol and report of the test method for determination of sodium hyaluronate by performing specificity, linearity, accuracy and precision.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of batch manufacturing record of stability batches of drug product.
6.		

Decision of 321st meeting of Registration Board:

Deferred for following submissions:

- Confirmation of required manufacturing facility / section from Licensing Division.
- Evidence of approval of applied formulation either as pharmaceutical drug product or medical device in reference regulatory authorities/agencies which were adopted by the Registration Board.
- Clarification of source of drug substance whether Biological or synthetic.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Confirmation of required manufacturing facility / section from Licensing Division.	Firm has submitted copy of inspection report dated 17-10-2018 and 22-11-2018 which specifies Ampoule (General) section. Firm further submitted that our Injectable Ampoule General section was approved by the CLB and it consist of 2 separate assembly lines for manufacturing of Ampoules and Prefilled syringe, Moreover, one our product Sunny D Pre-filled Syring was recently approved in 321st meeting by the DRB-DRAP with the same dosage form.
2.	Evidence of approval of applied formulation either as pharmaceutical drug product or medical device in reference regulatory authorities/agencies which were adopted by the Registration Board.	The product HYALGAN 20 mg/2ml PFS approved by French Public Health Agency. HYALGAN 20 mg/2 ml, solution for injection for intra-articular route in pre-filled syringe is approved by ANSM France.
3.	Clarification of source of drug substance whether Biological or synthetic. Response by the firm: Sodium hyaluronate is a pure chemical substance with de For characterisation of sodium hyaluronate (pure chemical substance) is necessary *only* physico-chemical-biological testing in accordance with European pharmacopoeia. Parametric release is not necessary, but of course the production process and its control is in accordance with GMP. Moreover, the substance (or its characteristics) is not mention in the list of the products to be considered as biological medicinal products. For our Sodium hyaluronate is a Certificate of Suitability (CEP) granted. CEP is not granted for biologicals fined chemical structure, characteristics and properties. Firm has further submitted copy of a letter from Contipro, Czech Republic dated 25-01-2023. The letter specifies the following: *Sodium hyaluronate is a pure chemical substance with defined chemical structure, characteristics and properties. Despite it is of biotechnological origin manufactured by classical fermentation of bacteria Streptococcus sp. And sometimes referenced in the scientific literature as a biological substance (meaning that the substance is a naturally produced in living organisms), it is not considered as biological substance in accordance with the directive 2001/83/EC, Annex I, Part 1, Module 3, chapter 3.2.1. Active substance(s),* *subchapter 3.2.1.1., letter b)* *A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control. The following shall be considered as biological medicinal products: immunological medicinal products and medicinal products derived from human blood and human plasma as defined, respectively in paragraphs (4) and (10) of Article 1; medicinal products falling within the scope of Part A of the Annex to Regulation (EEC) No 2309/93; advanced therapy medicinal products as defined in Part IV of this Annex.* *Explanation: For characterisation of sodium hyaluronate (pure chemical substance) is necessary only physico-chemical-biological testing in accordance with European pharmacopoeia. Parametric release is not necessary. But, of course, the production process and its control are in accordance with GMP.* *Moreover, the substance (or its characteristics) is not mentioned in the list of the products to be considered as biological medicinal products.*	

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.**
- **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, before issuance of Registration letter.**

38.	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. 8918 Dated 07-04-2022
	Details of fee submitted	PKR 30,000/-: Dated 25-01-2022
	The proposed proprietary name / brand name	ALDROX 500mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefadroxil 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 specifications
	Proposed Pack size	2 x 6's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefadroxil 500 mg Capsules. MHRA approved
	For generic drugs (me-too status)	Sokxil 500mg Capsules. Reg. NO. 54925
	GMP status of the Finished product manufacturer	New license granted on 22-09-2020.
	Name and address of API manufacturer.	M/s Pharmagen Limited., Address: Kot nabi Buksh 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, 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 Cefadroxil 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 36 months Accelerated: 40°C±2°C/75% ± 5% RH for 6 months Batches: (00221/001, 00221/002, 00221/003)
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product of Loxadril 500mg capsule (Batch #) by Himont pharma Pakistan Limited by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Loxadril 500mg capsule 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 Pharmagen Limited., Address: Kot nabi Bukshwala, 34-Km, Ferozpur Road, Lahore.		
API Lot No.	00243 / 160 / 2021		
Description of Pack (Container closure system)	Blister pack of 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

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate.
3.	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.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks OF Evaluator:

Sr.#	Section	Observation	Response of firm
2	**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.	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 have been submitted.
3	**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.
4.	**3.2.S.4.4**	• The submitted COA of drug substance manufacturer is of Cefadroxil as monohydrate while identification shows Cefixime reference standard. Moreover, text editing in the COA is evident which is creating doubt. • The limits of water contents of drug substance are different from USP monograph. • The tests of optical rotation, crystallinity are not performed by drug substance manufacturer as recommended by Pharmacopoeia.	As per firm 'Mistakenly the COA of Cefixime compacted was submitted. However, in provided COA limits/tests are not in accordance with USP monograph'.
5	**3.2.S.4.5**	This section mentions that cefixime is a pharmacopoeial product. Clarification is required.	As per firm "Due to a typographic mistake cefixime is written instead of cefadroxil.
6	**3.2.S.5**	Provide COAs of reference standards used in the analysis of drug substance including source and lot number.	Firm has provided working standard COA of Batch no.: 002200/06/2021.
7	**3.2.P.1**	• Submit master formulation including theoretical fill weight per capsule alongwith details of equivalency factor for cefadroxil monhydrate. • 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).	• Firm has Submitted master formulation including theoretical fill weight per bottle alongwith details of equivalency factor for cefadroxil monohydrate.
8	**3.2.P.2.2.1**	• Justify why pharmaceutical equivalence and CDP studies have not been performed against innovator product. • Justify how same results are obtained for pharmaceutical equivalence and CDP studies for both Cefadroxil 250mg Capsule and Cefadroxil 500mg Capsule.	• Due to un availability of innovator pack. • Firm has stated that CDP esults of both products are different.
9	**3.2.P.2.2.2.4**	Justify why the tests of reconstitution time, clarity and color after reconstitution are included in this section. Moreover, flow chart of manufacturing also showed the process for dry powder for suspension.	Firm has stated that both reconstitution test and test for clarity of solution are for Ceftriaxone injection, while drafting these test appeared in these section. Firm has

			provided revised specifications
10	**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
11	**3.2.P.5.1**	• The submitted specification does not include test for dissolution, uniformity of dosage units and water determination as recommended by USP. Moreover, justify the addition of tests of pH, loss on drying, weight variation, BET and sterility test in the specifications of Cefadroxil capsule.	Firm has submitted revised specification. However, fee for such change has not been submitted.
12	**3.2.P.5.2**	Submit analytical procedures of Cefadroxil capsule stating actual concentrations of sample and standard instead of submitting USP monograph.	Submitted
13	**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 and specificity test including the details of concentration of 80%, 100% and 120% solutions.	Submitted
14	**3.2.P.6**	Provide COA of reference standard used in the analysis of drug product including source and lot number.	Form has provided COA of Cefadroxil (compacted), Batch no. 002201/07/2021.
15	**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 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. • 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 Batch Manufacturing Record (BMR) for the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3. • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted Not submitted Data sheets are missing. Firm has provided Performa Invoice of procurement of 25 kg Cefadroxil (Micronized) and 25 kg Cefadroxil (compacted). Submitted. Not submitted

Decision of 322nd meeting of Registration Board:
Deferred the case for following submissions:
• COA from drug substance and drug product manufacturer in accordance with pharmacopoeia.

- Submission of the valid copy of GMP Certificate of Drug substance manufacturer.
- Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets involving the performance of all pharmacopoeial tests.
- 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.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	COA from drug substance and drug product manufacturer in accordance with pharmacopoeia.	Firm has submitted COA of API from API manufacturer.
2.	Submission of the valid copy of GMP Certificate of Drug substance manufacturer.	Firm has submitted copy of GMP certificate of API manufacturer issued on the basis of inspection dated 08-01-2019.
3.	Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets involving the performance of all pharmacopoeial tests.	Firm has submitted stability data of 3 batches along with raw data sheets and chromatograms.
4.	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 7,500 fee vide slip number 61268061 dated 22-02-2023.

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.**

39.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gray's Pharmaceuticals. Plot No. 2, Street No. N-3, RCCI Rawat Rawalpindi.**
	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 15-12-2020.
	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 Lyophilized vial (General) 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 Lyophilized vial (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Lyophilized vial (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. 18913: 06-07-2021
	Details of fee submitted	PKR 50,000/-: 29-12-2020
	The proposed proprietary name / brand name	**LADAZOLE Injection 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Lansoprazole……30mg
	Pharmaceutical form of applied drug	Almost white coloured lyophilized hygroscopic powder contained in glass vial
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lansoprazole Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Qpro injection by Bosch Pharma
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Selanz 30mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.		
API Lot No.	ALAN 18001		
Description of Pack (Container closure system)	Glass vials		
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.	L-213	L-233	L-252
Batch Size	9500 Packs	9500 Packs	9500 Packs
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	17-08-2019	17-08-2019	17-08-2019
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)	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).	Firm has submitted copy of clearance certificate and invoice cleared by AD (I&E) specifying import of 3Kg lansoprazole powder.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted by the firm
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 by the firm

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document. Furthermore, it is also pertinent to mention that the drug product testing has been carried out using specifications which are not in line with the recommendations of the general monographs of the official pharmacopoeia and the analytical method of the assay test is based on UV method contrary to the method of analysis of the drug substance manufacturer and innovator's product.

Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the specifications of the drug product so that further evaluation of your application could be carried out.

Firm has now submitted application as per guidance document. However, the following observations are still not addressed.

- Verification studies of the analytical method of drug substance since the API used is non-lyophilized powder.
- pH of reference product is 9 – 10.5 while the limit set by firm is 9 – 12 and results are above 11.0
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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	Reason for deferment	Response by the firm
1.	Verification studies of the analytical method of drug substance since the API used is non-lyophilized powder.	Firm has submitted verification studies of the analytical method of drug substance.
2.	pH of reference product is 9 – 10.5 while the limit set by firm is 9 – 12 and results are above 11.0	Firm has submitted copy of USFDA label for Prevacid IV 30mg/vial which specifies that the solution prevacid has a pH of approximately 11 following the first reconstitution with sterile water for injection and approximately 10.2, 10 or 9.5 afer dilution with either 0.9% NaCl, lactated ringer of 5% dextrose injection respectively.
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of API manufacturer valid till 22-01-2023.
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC system.

Decision: Approved with Innovator's specifications.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **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, before issuance of Registration letter.**

40.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories, Plot # 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) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-12-2020.
	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 Lyophilized vial (General) 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 Lyophilized vial (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Lyophilized vial (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. 19156: 08-07-2021
	Details of fee submitted	PKR 50,000/-: 26-01-2021
	The proposed proprietary name / brand name	**ZOLARD Injection 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Lansoprazole……30mg
	Pharmaceutical form of applied drug	Almost white coloured lyophilized hygroscopic powder contained in glass vial
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lansoprazole Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Qpro injection by Bosch Pharma
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan 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 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Selanz 30mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
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.			
Batch Size			
Manufacturing Date			
Date of Initiation			
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.	
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.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

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

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document. Furthermore, it is also pertinent to mention that the drug product testing has been carried out using specifications which are not in line with the recommendations of the general monographs of the official pharmacopoeia and the analytical method of the assay test is based on UV method contrary to the method of analysis of the drug substance manufacturer and innovator's product.

Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the specifications of the drug product so that further evaluation of your application could be carried out.

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:

Firm has now submitted application as per guidance document. The details of the submitted stability data is as under:

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.		
API Lot No.	ALAN 18001		
Description of Pack (Container closure system)	Glass vials		
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.	L-213	L-233	L-252
Batch Size	9500 Packs	9500 Packs	9500 Packs
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	17-08-2019	17-08-2019	17-08-2019
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)	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).	Firm has submitted copy of clearance certificate and invoice cleared by AD (I&E) specifying import of 3Kg lansoprazole powder.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted by the firm
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 by the firm

Evaluation by PEC[3]:

However, few points which were not previously addressed by the manufacturer of same formulation in case of Ladazole Injection 30mg are also addressed and are placed below:

Sr. No	Points / observations	Response by the firm
1.	Verification studies of the analytical method of drug substance since the API used is non-lyophilized powder.	Firm has submitted verification studies of the analytical method of drug substance.
2.	pH of reference product is 9 – 10.5 while the limit set by firm is 9 – 12 and results are above 11.0	Firm has submitted copy of USFDA label for Prevacid IV 30mg/vial which specifies that the solution prevacid has a pH of approximately 11 following the first reconstitution with sterile water for injection and approximately 10.2, 10 or 9.5 afer dilution with either 0.9% NaCl, lactated ringer of 5% dextrose injection respectively.
3.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of API manufacturer valid till 22-01-2023.
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC system.

Decision: Approved with Innovator's specifications.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **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, before issuance of Registration letter.**

41.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sigma Pharma International (Pvt) Ltd. Plot # E-50, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Sigma Pharma International (Pvt) Ltd. Plot # E-50, North Western Industrial Zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-11-2020. The letter specifies Tablet (General) Section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-11-2020. The letter specifies Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24405: 20-11-2019

	Details of fee submitted	PKR 20,000/-: 19-11-2019
	The proposed proprietary name / brand name	**TRED SR 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated sustained release tablet contains: Tramadol HCl……100mg
	Pharmaceutical form of applied drug	White color round shaped film coated sustained release tablet with line of bisection on one side.
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Tramal SR Tablet by Searle
	Name and address of API manufacturer.	Supriya Lifescience Ltd., A-5/2, Lote Parshuram Industrial Area, M.I.D.C. Taluka – Khed, District – Ratnagiri, 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 drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Tramal SR Tablet by Searle. Firm has submitted results of CDP for their

		product against the comparator product Tramal SR Tablet by Searle. The CDP is performed in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Supriya Lifescience Ltd., A-5/2, Lote Parshuram Industrial Area, M.I.D.C. Taluka – Khed, District – Ratnagiri, Maharashtra, India		
API Lot No.	SLL/TDM/0121006		
Description of Pack (Container closure system)	Alu-PVC		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	6452 Tablet	6452 Tablet	6452 Tablet
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	06-07-2021	20-07-2021	28-07-2021
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)	No PSI of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6099317) issued by Food & Drugs Administration (Maharashtra State) India. The certificate is valid till 29-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice from Globe Chemicals GmbH cleared by AD (I&E) DRAP dated 22-04-2021. The invoice declare purchase of 300Kg Tramadol HCl.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC system is not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Firm has submitted initial application on Form 5F on 20-11-2019 before the start of process of CTD pre-submission screening. The initial application was without any product development or stability study data. Later in response to the letter of shortcoming the firm submitted product development and stability study data on 05-10-2021.
- The real time stability study data of API is till 12 months only.
- GMP certificate of API was valid till 29-04-2022.
- Real time stability study data was conducted at 0, 6, 12, 18, 24 month and does not include testing at 3 and 9 months.

Decision of 323rd meeting of Registration Board: Registration Board observed that the firm has submitted various documents at different time intervals and that completely compiled application is not submitted. The Board after thorough deliberation decided to defer the case for submission of complete application on Form 5-F as per the guidance document approved by Registration Board.
Response by the firm: The firm vide its reply Dy No. 4877 dated 20-02-2023 submitted complete application / dossier on Form 5-F (CTD) as per the CTD guidance document in a single submission in 2 volume dossiers. Firm has requested to consider this application.
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.**

42.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12294: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFESOL-RL IV Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride ……0.027g Potassium chloride……0.04g Sodium chloride…… 0.60g Sodium lactate….. ..0.32g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP

	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Could not be confirmed in applied strength
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Not submitted. **Calcium chloride:** Not submitted. **Potassium chloride:** Firm has submitted stability data of 3 batches of API as per zone IV-A conditions. **Sodium lactate:** Not submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Sterifluid-RL Infusion by M/s FDL Pharma."

	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 liters	300 liters	300 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909).

		Calcium chloride: Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee since innovator product specifies clalcium chloride dihydrate 0.027g/100ml while you have mentioned calcium chloride 0.027g/100ml.	*Applied formulation contains calcium chloride dihydrate as per BP innovator product also contains calcium chloride dihydrate. In master formulation typographic error found. New master formulation has been submitted.* **Firm has not revised the label claim nor submitted any fee.**
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	*our main competitor is FRONTIER DEXTROSE LIMITED PHARMA HATTAR having formulation sodium lactate 0.32g/100 ml which is same as our formulation 0.32g/100 ml.* **The available data base shows that Sterifluid RL Infusion (Reg # 052739) of M/s Frontier Dextrose Ltd contains Sodium Lactate 0.31gm**
3.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	*Typographic error found. Our product is BP Specifications.* **Firm has not submitted any fee**
4.	Submit verification studies of the Calcium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
5.	Provide actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer. Furthermore, the submitted stabilility sheets does not specify any batch number, manufacturing or expiry date etc.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
6.	Submit verification studies of the Potassium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
7.	Submit verification studies of the Sodium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**

8.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
9.	Submit verification studies of the sodium lactate drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
10.	Provide actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
11.	The innovator's product is using 0.027g/100ml of clalcium chloride dihydrate while your formulation contains 0.027g/100ml of calcium chloride. Justify how your formulation is similar to that of innovator's product.	*Our formulation is similar to that of innovators product that is 0.027g/100ml of clacium chloride dihydrate.* **The submitted formulation as well as BMR shows that firm is using 0.027g/100ml of calcium chloride.**
12.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*Because they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product.* **Firm has not submitted any relevant response.**
13.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation.* **Firm has not submitted any relevant response.**
14.	Justify how you can perform pharmaceutical equivalence against a product which have different quantitative composition as compared to your product.	*We cannot perform pharmaceutical equivalence against a product which has different quantitative composition to our product.* **Firm has not submitted any relevant response.**
15.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
16.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
17.	Justify why the drug product specifications does not contain test of particulate matter.	*Product specification concentrate on quality of product till expiry with 100% efficiency .detail is given by literature support.*

		Firm has not submitted any relevant response.
18.	Justify why the acceptance criteria of all assay tests in pharmaceutical equivalence is not as per BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
19.	Justify why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
20.	Justify why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*Potassium test is according to BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
21.	Justify why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	*The method of sodium lactate is HPLC method in BP 2022. We give the HPLC print is attached with the file.* **Firm has used titration method as submitted in the application.**
22.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies.* **Firm has submitted process validation report instead of analytical method verification.**
23.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
24.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
25.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*At present we are using simple cap to reduce cost of our product but we have the facility of Eurocap machine facility.*
26.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*40 bottles in real stabilty chamber.* *60 bottles in accelerated stabilty chamber.*
27.	Justify why the stability studies have been performed using method and acceptance criteria which is completely different from that specified in BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
28.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
29.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**

30.	The analytical method in section 3.2.P.5.2 specifies titration method for analysis of lactate while in stability studies you have provided single HPLC chromatogram for analysis in which the UV wavelength is also different from that specified in BP monograph.	*we have sumbitted the sodium lactate method on hplc according to BP2022.* **Firm has not submitted any relevant response.**
31.	Justify how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	**Firm has not submitted any response.**
32.	Provide details of the HPLC system, model along with details of the software available in your QC lab and status of its 21 CFR compliance.	*Our HPLC is LAB SOLUTION 21CFR software in our labortaory.*
33.	Provide evidence of atomic emission spectroscopy required for analysis of drug product as per BP monograph.	**Firm has not submitted any response.**
34.	Provide analysis report for all the testing performed through atomic emission spectroscopy.	**Firm has not submitted any response.**

Decision of 323rd meeting of Registration Board:

Deferred for following submissions:

- Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.
- Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.
- Report of verification studies of the Calcium chloride drug substance.
- Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the Potassium chloride drug substance.
- Report of verification studies of the Sodium chloride drug substance.
- Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the sodium lactate drug substance.
- Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.
- Pharmaceutical equivalence studies against the innovator's product.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Scientific justification for the drug product specifications which does not contain test of particulate matter.
- Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.
- Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.
- Report of verification studies of the analytical method of drug product.
- Scientific justification why the test of water loss is not performed during the stability studies.
- Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.

- Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.
- Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.
- Batch size of drug product stability batches in terms of no. of units.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.	Firm has revised the label claim as per innovator's product
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	Our me-too competitor is FDL which have 0.32g/100ml
3.	Report of verification studies of the Calcium chloride drug substance.	Not submitted
4.	Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
5.	Report of verification studies of the Potassium chloride drug substance.	Not submitted
6.	Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
7.	Report of verification studies of the sodium lactate drug substance.	Not submitted
8.	Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
9.	Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.	Our formulation is similar to that of innovator's product
10.	Pharmaceutical equivalence studies against the innovator's product.	Not submitted againt the innovator's product
11.	Submission of microbiological attributes of the drug product in section 3.2.P.2.5.	Not submitted.
12.	Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.	No justification is submitted by the firm.
13.	Scientific justification for the drug product specifications which does not contain test of particulate matter.	Not submitted.
14.	Scientific justification for having different acceptance criteria of all assay tests in specifications as	No justification is submitted.

	compared to that specified in BP monograph.	
15.	Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
16.	Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
17.	Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	No justification submitted.
18.	Report of verification studies of the analytical method of drug product.	Not submitted.
19.	Scientific justification why the test of water loss is not performed during the stability studies.	Submitted by the firm.
20.	Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	No justification submitted.
21.	Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.	Not submitted.
22.	Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.	Not submitted.
23.	Batch size of drug product stability batches in terms of no. of units.	100 bottles

Decision: Deferred for following submissions:

- **Revision of label claim of the applied product as per the innovator's product and labelling requirements of BP monograph along with submission of full fee of registration.**
- **Protocol and report of verification studies of the Calcium chloride drug substance as per the ICH Q2 Guidelines.**
- **Scientific justification for initial submission of stability study data of the calcium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.**
- **Protocol and report of verification studies of the Potassium chloride drug substance as per the ICH Q2 Guidelines.**
- **Protocol and report of verification studies of the Sodium chloride drug substance as per the ICH Q2 Guidelines.**
- **Scientific justification for initial submission of stability study data of the sodium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.**
- **Protocol and report of verification studies of the sodium lactate drug substance as per the ICH Q2 Guidelines.**

- **Scientific justification for initial submission of stability study data of the Sodium lactate drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.**
- **Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.**
- **Submission of picture / image of the innovator's product against which Pharmaceutical equivalence studies have been performed.**
- **Submission of microbiological attributes of the drug product in section 3.2.P.2.5.**
- **Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.**
- **Scientific justification for the drug product specifications which does not contain test of particulate matter.**
- **Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.**
- **Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
- **Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
- **Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.**
- **Protocol and report of verification studies of the analytical method of drug product as per the ICH Q2 Guidelines.**
- **Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.**
- **Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.**
- **Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.**

43.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 12295: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFESOL-RL IV Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride ……0.027g Potassium chloride……0.04g Sodium chloride…… 0.60g Sodium lactate….. ..0.32g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Could not be confirmed
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Not submitted. **Calcium chloride:** Not submitted. **Potassium chloride:** Firm has submitted stability data of 3 batches of API as per zone IV-A conditions. **Sodium lactate:** Not submitted.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Sterifluid-RL Infusion by M/s FDL Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 liters	300 liters	300 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by

		China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee since innovator product specifies clalcium chloride dihydrate 0.027g/100ml while you have mentioned calcium chloride 0.027g/100ml.	*Applied formulation contains calcium chloride dihydrate as per BP innovator product also contains calcium chloride dihydrate. In master formulation typographic error found. New master formulation has been submitted.* **Firm has not revised the label claim nor submitted any fee.**
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	*our main competitor is FRONTIER DEXTROSE LIMITED PHARMA HATTAR having formulation sodium lactate 0.32g/100 ml which is same as our formulation 0.32g/100 ml.* **The available data base shows that Sterifluid RL Infusion (Reg # 052739) of M/s Frontier Dextrose Ltd contains Sodium Lactate 0.31gm**
3.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	*Typographic error found. Our product is BP Specifications.* **Firm has not submitted any fee**
4.	Submit verification studies of the Calcium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
5.	Provide actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real	**Firm has not submitted stability study data sheets for API from API manufacturer.**

	time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer. Furthermore, the submitted stabilility sheets does not specify any batch number, manufacturing or expiry date etc.	
6.	Submit verification studies of the Potassium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
7.	Submit verification studies of the Sodium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
8.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
9.	Submit verification studies of the sodium lactate drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
10.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
11.	The innovator's product is using 0.027g/100ml of clalcium chloride dihydrate while your formulation contains 0.027g/100ml of calcium chloride. Justify how your formulation is similar to that of innovator's product.	*Our formulation is similar to that of innovators product that is 0.027g/100ml of clacium chloride dihydrate.* **The submitted formulation as well as BMR shows that firm is using 0.027g/100ml of calcium chloride.**
12.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*Because they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product.* **Firm has not submitted any relevant response.**
13.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation.* **Firm has not submitted any relevant response.**
14.	Justify how you can perform pharmaceutical equivalence against a product which have different quantitative composition as compared to your product.	*We cannot perform pharmaceutical equivalence against a product which has different quantitative composition to our product.*

		Firm has not submitted any relevant response.
15.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
16.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
17.	Justify why the drug product specifications does not contain test of particulate matter.	*Product specification concentrate on quality of product till expiry with 100% efficiency .detail is given by literature support.* **Firm has not submitted any relevant response.**
18.	Justify why the acceptance criteria of all assay tests in pharmaceutical equivalence is not as per BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
19.	Justify why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
20.	Justify why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*Potassium test is according to BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
21.	Justify why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	*The method of sodium lactate is HPLC method in BP 2022. We give the HPLC print is attached with the file.* **Firm has used titration method as submitted in the application.**
22.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies.* **Firm has submitted process validation report instead of analytical method verification.**
23.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
24.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
25.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*At present we are using simple cap to reduce cost of our product but we have the facility of Eurocap machine facility.*
26.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*40 bottles in real stabilty chamber.* *60 bottles in accelerated stabilty chamber.*

27.	Justify why the stability studies have been performed using method and acceptance criteria which is completely different from that specified in BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
28.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
29.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**
30.	The analytical method in section 3.2.P.5.2 specifies titration method for analysis of lactate while in stability studies you have provided single HPLC chromatogram for analysis in which the UV wavelength is also different from that specified in BP monograph.	*we have sumbitted the sodium lactate method on hplc according to BP2022.* **Firm has not submitted any relevant response.**
31.	Justify how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	**Firm has not submitted any response.**
32.	Provide details of the HPLC system, model along with details of the software available in your QC lab and status of its 21 CFR compliance.	*Our HPLC is LAB SOLUTION 21CFR software in our labortaory.*
33.	Provide evidence of atomic emission spectroscopy required for analysis of drug product as per BP monograph.	**Firm has not submitted any response.**
34.	Provide analysis report for all the testing performed through atomic emission spectroscopy.	**Firm has not submitted any response.**

Decision of 323rd meeting of Registration Board:

Deferred for following submissions:

- Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.
- Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.
- Report of verification studies of the Calcium chloride drug substance.
- Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the Potassium chloride drug substance.
- Report of verification studies of the Sodium chloride drug substance.
- Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the sodium lactate drug substance.
- Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.
- Pharmaceutical equivalence studies against the innovator's product.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Scientific justification for the drug product specifications which does not contain test of particulate matter.

- Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.
- Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.
- Report of verification studies of the analytical method of drug product.
- Scientific justification why the test of water loss is not performed during the stability studies.
- Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.
- Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.
- Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.
- Batch size of drug product stability batches in terms of no. of units.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.	Firm has revised the label claim as per innovator's product
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	Our me-too competitor is FDL which have 0.32g/100ml
3.	Report of verification studies of the Calcium chloride drug substance.	Not submitted
4.	Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
5.	Report of verification studies of the Potassium chloride drug substance.	Not submitted
6.	Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
7.	Report of verification studies of the sodium lactate drug substance.	Not submitted
8.	Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
9.	Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using	Our formulation is similar to that of innovator's product

	0.027g/100ml of clalcium chloride dihydrate.	
10.	Pharmaceutical equivalence studies against the innovator's product.	Not submitted againt the innovator's product
11.	Submission of microbiological attributes of the drug product in section 3.2.P.2.5.	Not submitted.
12.	Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.	No justification is submitted by the firm.
13.	Scientific justification for the drug product specifications which does not contain test of particulate matter.	Not submitted.
14.	Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.	No justification is submitted.
15.	Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
16.	Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
17.	Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	No justification submitted.
18.	Report of verification studies of the analytical method of drug product.	Not submitted.
19.	Scientific justification why the test of water loss is not performed during the stability studies.	Submitted by the firm.
20.	Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	No justification submitted.
21.	Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.	Not submitted.
22.	Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.	Not submitted.
23.	Batch size of drug product stability batches in terms of no. of units.	100 bottles
Decision: Deferred for following submissions:		

- **Revision of label claim of the applied product as per the innovator's product and labelling requirements of BP monograph along with submission of full fee of registration.**
- **Protocol and report of verification studies of the Calcium chloride drug substance as per the ICH Q2 Guidelines.**
- **Scientific justification for initial submission of stability study data of the calcium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.**
- **Protocol and report of verification studies of the Potassium chloride drug substance as per the ICH Q2 Guidelines.**
- **Protocol and report of verification studies of the Sodium chloride drug substance as per the ICH Q2 Guidelines.**
- **Scientific justification for initial submission of stability study data of the sodium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.**
- **Protocol and report of verification studies of the sodium lactate drug substance as per the ICH Q2 Guidelines.**
- **Scientific justification for initial submission of stability study data of the Sodium lactate drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.**
- **Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.**
- **Submission of picture / image of the innovator's product against which Pharmaceutical equivalence studies have been performed.**
- **Submission of microbiological attributes of the drug product in section 3.2.P.2.5.**
- **Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.**
- **Scientific justification for the drug product specifications which does not contain test of particulate matter.**
- **Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.**
- **Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
- **Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
- **Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.**
- **Protocol and report of verification studies of the analytical method of drug product as per the ICH Q2 Guidelines.**
- **Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.**
- **Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.**
- **Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.**

Case No. 03 Registration applications of Form-5 cases

a) New cases

44.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Prokin Tablet 1mg
	Composition	Each Tablet Contains:

	Cinitapride…1mg
Diary No. Date of R& I & fee	Dy No. 14091: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Propulsives
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.	Spain Approved
Me-too status	Cidine 1mg Tablet by Highnoon Laboratories
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
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 Tablet Contains: Cinitapride as Hydrogen Tartrate……1mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Tablet Contains:
Cinitapride as Hydrogen Tartrate……1mg

- **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.**

45. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Zeto Tablet 50mg
Composition	Each Tablet Contains: Itopride HCl…50mg
Diary No. Date of R& I & fee	Dy No. 14088: 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	• Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Itopride HCl……50mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Itopride HCl……50mg
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.

46. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Zeto Tablet 150mg
Composition	Each Tablet Contains: Itopride HCl…150mg
Diary No. Date of R& I & fee	Dy No. 14089: 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.	Could not be confirmed
Me-too status	Ganaton OD Tablet by Abbott
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

47. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Synleo Tablet 2.5mg
Composition	Each Tablet Contains: Letrozole…2.5mg
Diary No. Date of R& I & fee	Dy No. 14085: 07-03-2019 PKR 20,000/-: 07-03-2019
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 on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	• Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Letrozole…2.5mg

Decision: Approved with following label claim:
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.

48. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Synpride 50mg Tablet
Composition	Each Tablet Contains: Levosulpride…50mg
Diary No. Date of R& I & fee	Dy No. 14090: 07-03-2019 PKR 20,000/-: 07-03-2019
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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

49. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Synman 10mg Tablet
Composition	Each Tablet Contains: Memantine HCl…10mg

Diary No. Date of R& I & fee	Dy No. 14078: 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	•

Decision: Approved.

50.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Malphine Injection 22.75mg
	Composition	Each ml Contains: Pheniramine Maleate…22.75mg
	Diary No. Date of R& I & fee	Dy No. 14094: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	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.	Could not be confirmed
	Me-too status	Amrovil Injection by Amros
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

51.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Syntam Tablet 10mg
	Composition	Each Tablet Contains: Quetiapine As Fumarate…10mg
	Diary No. Date of R& I & fee	Dy No. 14081: 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.	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 22-01-2021.
	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.**

52.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Syntam Tablet 100mg
	Composition	Each Tablet Contains: Quetiapine as Fumarate…100mg
	Diary No. Date of R& I & fee	Dy No. 14084: 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Quetiapine as Fumarate…100mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Quetiapine as Fumarate…100mg
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.

53.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Synline Tablet 100mg
	Composition	Each Tablet Contains: Sertraline HCl…100mg
	Diary No. Date of R& I & fee	Dy No. 14000: 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.	MHRA Approved
	Me-too status	Serbeen Tablet by Horizon
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product along with submission of full fee as per following: Each Film Coated Tablet Contains: Sertraline (as HCl)…100mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Sertraline (as HCl)…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.

54.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Synline Tablet 150mg
	Composition	Each Tablet Contains: Sertraline Hcl…150mg

Diary No. Date of R& I & fee	Dy No. 14079: 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.	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 22-01-2021.
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.**

55. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Sitasyn Tablet 50/1000mg
Composition	Each Tablet Contains: Sitagliptin…50mg Metformin HCl…1000mg
Diary No. Date of R& I & fee	Dy No. 14083: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antidiabetic
Type of Form	Form 5
Finished Product Specification	Innovator's specs
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 has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product along with submission of full fee 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

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.

56. Name and address of manufacturer / Applicant	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
Brand Name +Dosage Form + Strength	Synfine Tablet 125mg
Composition	Each Tablet Contains: Terbinafine HCl…125mg
Diary No. Date of R& I & fee	Dy No. 14076: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antifungal
Type of Form	Form 5

Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	LAMISIL tablet TGA Australia Approved
Me-too status	Terbitec Tablet by Fynk Pharma
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	•

Decision: Approved.

57.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Synfine Tablet 250mg
	Composition	Each Tablet Contains: Terbinafine HCl…250mg
	Diary No. Date of R& I & fee	Dy No. 14077: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL tablet TGA Australia Approved
	Me-too status	Terbitec Tablet by Fynk Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

58.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Movin Tablet 2mg
	Composition	Each Tablet Contains: Tizanidine HCl…2mg
	Diary No. Date of R& I & fee	Dy No. 14086: 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.	MHRA Approved
	Me-too status	Movax Tablet by Sami
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
	Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product along with submission of full fee as per following: Each Film Coated Tablet Contains: Tizanidine (as HCl)…2mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Tizanidine (as HCl)…2mg

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.

59.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Movin Tablet 4mg
	Composition	Each Tablet Contains: Tizanidine HCl…4mg
	Diary No. Date of R& I & fee	Dy No. 14087: 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.	MHRA Approved
Me-too status	Movax Tablet by Sami
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product along with submission of full fee as per following: Each Film Coated Tablet Contains: Tizanidine (as HCl)…4mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Tizanidine (as HCl)…4mg

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.

60.	**Name and address of manufacturer / Applicant**	**M/s Synchro Pharmaceuticals 77-Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Dolysin Injection 50mg
	Composition	Each 2ml ampoule Contains: Tramadol HCl…100mg
	Diary No. Date of R& I & fee	Dy No. 14095: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Analgesic
	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	Trapam Injection by Islam Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 22-01-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

61.	**Name and address of manufacturer / Applicant**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Megaclop Tablet 75mg
	Composition	Each Film Coated Tablet Contains: Clopidogrel Bisulphate…75mg
	Diary No. Date of R& I & fee	Dy No. 17255: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	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	Lowplat tablet by Pharmevo
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Clopidogrel as Bisulphate…75mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Clopidogrel as Bisulphate…75mg

- **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.**

62.	**Name and address of manufacturer / Applicant**	**M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Poxitine Tablets 37.5mg
	Composition	Each Film Coated Tablet Contains: Paroxetine as HCl …37.5mg
	Diary No. Date of R& I & fee	Dy No. 17254: 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	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: 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.**

63.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zamtrine 20/120mg Tablet
	Composition	Each Tablet Contains: Artemether…20mg Lumefantrine…120mg
	Diary No. Date of R& I & fee	Dy No. 16385: 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.	RIAMET Tablet WHO PQ formulation
	Me-too status	Mefantrin Tablet by Jinnah Pharma
	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.

Decision: Approved.

- **Registration letter will be issued after submission of updated GMP inspection report by the firm.**

64.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**

Brand Name +Dosage Form + Strength	Zamtrine DS 40/240mg Tablet
Composition	Each Tablet Contains: Artemether…40mg Lumefantrine…240mg
Diary No. Date of R& I & fee	Dy No. 16386: 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	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.

Decision: Approved.

- **Registration letter will be issued after submission of updated GMP inspection report by the firm.**

65. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Zamtrine ES 80/480mg Tablet
Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
Diary No. Date of R& I & fee	Dy No. 16387: 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	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.

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 Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Zamtrol 50mg Tablet SR
Composition	Each Tablet Contains: Diclofenac Potassium…50mg
Diary No. Date of R& I & fee	Dy No. 16379: 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.	MHRA Approved
Me-too status	Maxit Tablet by Hilton
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.

- Revise the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee:
  Each Film Coated Tablet Contains:
  Diclofenac Potassium…50mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Diclofenac Potassium…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 uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

67. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	E Zole 40mg Tablet
Composition	Each Tablet Contains: Esomeprazole Magnesium…40mg
Diary No. Date of R& I & fee	Dy No. 16378: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	PPI
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Emzol Tablet by Metro Pharma
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. • Revise the label claim as per the innovator's product as under along with submission of full fee of registration: Each Delayed Release Tablet Contains: Esomeprazole (as magnesium trihydrate) …40mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Delayed Release Tablet Contains:
Esomeprazole (as magnesium trihydrate) …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.**

68. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Zamadin 40mg Tablet
Composition	Each Film Coated Tablet Contains: Famotidine…40mg
Diary No. Date of R& I & fee	Dy No. 16377: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antiulcer
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	Famikid Tablet by Karsons Pharma
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.

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 Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Fexadin Tablet 120mg
	Composition	Each Film coated Tablet Contains: Fexofenadine HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 16382: 07-03-2019 PKR 20,000/-: 06-03-2019
	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.	MHRA Approved
	Me-too status	Fexet Tablets by Getz
	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

70.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Fexadin Tablet 180mg
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…180mg
	Diary No. Date of R& I & fee	Dy No. 16381: 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.	MHRA Approved
	Me-too status	Fexet Tablets by Getz
	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

71.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Corphil Plus 80/80mg
	Composition	Each Sugar Coated Tablet Contains: Phloroglucinol Hydrate…80mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Dy No. 16395: 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	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

72.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Iro Plus 100mg Capsule
	Composition	Each Capsule Contains Iron Hydroxide Polymaltose Complex Eq To Elemental Iron…100mg
	Diary No. Date of R& I & fee	Dy No. 16782: 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	Iroplex Capsule by Pharmix
	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. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.

- **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 Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ezitam 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy No. 16393: 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	Lumark Tablet by Searle
	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.

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 Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ezitam 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 16392: 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	Lumark Tablet by Searle
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.

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 Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ezitam 750mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…750mg
	Diary No. Date of R& I & fee	Dy No. 16391: 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	Lumark Tablet by Searle
	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.

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 Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	All one 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Levocetrizine Dihydrochloride…5mg
	Diary No. Date of R& I & fee	Dy No. 16380: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihistaminic
	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	BELAIR 5mg Tablet by BAYER
	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

77.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Mever 200mg SR Capsule
	Composition	Each Capsule Contains: Mebeverine HCl (as SR Pellets)..…200mg
	Diary No. Date of R& I & fee	Dy No. 16404: 07-03-2019

	PKR 20,000/-: 07-03-2019
Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
Type of Form	Form 5
Finished Product Specification	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	Sameb MR 200mg Capsule by Hilton Pharma
GMP status	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad. • 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.

78.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Cormox Capsule 400mg
	Composition	Each Capsule Contains Moxifloxacin as HCl eq to Moxifloxacin…400mg
	Diary No. Date of R& I & fee	Dy No. 16407: 07-03-2019 PKR 20,000/-: 07-03-2019
	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.	MHRA Approved
	Me-too status	Avelox Tablet by Bayer
	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. • Revise the label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Moxifloxacin As HCl…400mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Moxifloxacin as HCl…400mg

- **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.**

79.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Orat 60mg Capsule
	Composition	Each Capsule Contains Orlistat (as IR Pellets)…60mg
	Diary No. Date of R& I & fee	Dy No. 16408: 07-03-2019 PKR 20,000/-: 07-03-2019
	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.	MHRA Approved
	Me-too status	Zerolite Capsule by Crystolite
	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:

- **Updated GMP inspection report conducted within aperiod of last 3 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.**

80. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Rabezole 10mg Capsule
Composition	Each Capsule Contains: Rabeprazole Sodium Enteric Coated Pellets…10mg
Diary No. Date of R& I & fee	Dy No. 16403: 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.	Could not be confirmed
Me-too status	Repit Capsule by Shrooq Pharma
GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
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. • 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).

Decision: Deferred for following:

- **Updated GMP inspection report conducted within aperiod of last 3 years.**
- **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).**

81. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Rabezole 20mg Capsule
Composition	Each Capsule Contains: Rabeprazole Sodium Enteric Coated Pellets…20mg
Diary No. Date of R& I & fee	Dy No. 16402: 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.	Could not be confirmed
Me-too status	Repit Capsule by Shrooq Pharma
GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.

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. • 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).

Decision: Deferred for following:

- **Updated GMP inspection report conducted within aperiod of last 3 years.**
- **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).**

82.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rivaban 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy No. 16390: 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	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

83.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rivaban 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy No. 16388: 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	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

84.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rivaban 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg

Diary No. Date of R& I & fee	Dy No. 16389: 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	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.

Decision: Approved.
Registration letter will be issued after submission of updated GMP inspection report by the firm.

85. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Rosatin 5mg Tablet
Composition	Each Tablet Contains: Rosuvastatin Calcium…5mg
Diary No. Date of R& I & fee	Dy No. 16375: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	HMG CoA reductase 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	Crestat Tablet by CCL
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. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)…5mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)…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.**

86. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Rosatin 10mg Tablet
Composition	Each Tablet Contains: Rosuvastatin Calcium…10mg
Diary No. Date of R& I & fee	Dy No. 16374: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	HMG CoA reductase 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	Crestat Tablet by CCL
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. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)…10mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)…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.**

87. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Rosatin 20mg Tablet
Composition	Each Tablet Contains: Rosuvastatin Calcium…20mg
Diary No. Date of R& I & fee	Dy No. 16376: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	HMG CoA reductase 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	Crestat Tablet by CCL
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. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)…20mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)…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.**

88. Name and address of manufacturer / Applicant	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Urisin 0.4mg Capsule
Composition	Each Capsule Contains: Tamsulosin HCl…0.4mg
Diary No. Date of R& I & fee	Dy No. 16401: 07-03-2019 PKR 20,000/-: 07-03-2019
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	Inspection date 13/07/2018, panel recommend grant of DML
Remarks of the Evaluator[3].	• **Source of pellets:** M/s Vision Pharmaceuticals, Islamabad.

- Latest GMP inspection report conducted within a period of last three years.
- 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.**

89.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ursolic 250mg capsule
	Composition	Each Capsule Contains Ursodeoxycholic Acid …250mg
	Diary No. Date of R& I & fee	Dy No. 16399: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications but available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ursodol capsule by Aspin Pharma
	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.

Decision: Approved with BP 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.**

90.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ursolic 500mg capsule
	Composition	Each Capsule Contains Ursodeoxycholic Acid …500mg
	Diary No. Date of R& I & fee	Dy No. 16398: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications but available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bilheptil 500mg hard capsules MHRA Approved
	Me-too status	Ursodol capsule by Aspin Pharma
	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.

Decision: Approved with BP 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.**

91.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Venafax XL 75mg Capsule
	Composition	Each Capsule Contains Venlafaxine HCl SR Pellets eq to Venlafaxine…75mg
	Diary No. Date of R& I & fee	Dy No. 16400: 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.	USFDA Approved
	Me-too status	Venwell Capsule by Fynk
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad. • 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.

92.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Voricon 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Voriconazole…50mg
	Diary No. Date of R& I & fee	Dy No. 16384: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimycotics 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.	USFDA Approved
	Me-too status	Dynazole Tablet by Dyson
	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.

Decision: Approved with JP 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.**

93.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Voricon 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
	Diary No. Date of R& I & fee	Dy No. 16383: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimycotics 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.	USFDA Approved
	Me-too status	Dynazole Tablet by Dyson

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.

Decision: Approved with JP 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.**

94. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Telpine Tablet 5mg/80mg
Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Telmisartan…80mg
Diary No. Date of R& I & fee	Dy No. 13893: 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	Am-Telsan Tablet by Hilton
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Evidence of bilayer tablet machine since the applied product is available as bilayer tablet in reference regulatory authorities. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each bilayer tablet Contains: Amlodipine as Besylate…5mg Telmisartan…80mg

Decision: Approved as per following label claim:

Each bilayer tablet Contains:
Amlodipine as Besylate…5mg
Telmisartan…80mg

Registration letter will be issued upon submission of fee of Rs. 7500/- for correction/pre-approval change in product description to bilayer tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with evidenceof availability of "bilayer tablet compression machine".

95. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Medirol Tablet 10mg
Composition	Each Film Coated Tablet Contains: Bambuterol HCl…10mg
Diary No. Date of R& I & fee	Dy No. 13818: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Selective beta-2-adrenoreceptor agonists
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	Bamberol Tablet by Swiss
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.

Remarks of the Evaluator[3].	• Firm has revised the label claim to uncoated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Tablet Contains: Bambuterol HCl…10mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Tablet Contains:
Bambuterol HCl…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.

96. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Medirol Tablet 20mg
Composition	Each Film Coated Tablet Contains: Bambuterol HCl…20mg
Diary No. Date of R& I & fee	Dy No. 13843: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Selective beta-2-adrenoreceptor agonists
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	Bamberol Tablet by Swiss
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Firm has revised the label claim to uncoated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Tablet Contains: Bambuterol HCl…20mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Tablet Contains:
Bambuterol HCl…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.

97. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	CT Med Syrup 30ml
Composition	Each 5ml Contains: Citicoline as Sodium…500mg
Diary No. Date of R& I & fee	Dy No. 13864: 07-03-2019 PKR 20,000/-: 06-03-2019
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.	SOMAZINE 100 mg/ml Oral Solution CIMA Spain Approved
Me-too status	Citicode Syrup by Rotex Pharma
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

98. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Lorich D Syrup 60ml
Composition	Each ml Contains Desloratadine…0.5mg

Diary No. Date of R& I & fee	Dy No. 13881: 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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

99.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexlan Capsule 60mg
	Composition	Each Capsule Contains Dexlansoprazole As Enteric Coated Pellets…60mg
	Diary No. Date of R& I & fee	Dy No. 13825: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	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.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	•

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.

100.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	E Cox Tablet 60mg
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy No. 13895: 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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

101.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	G Pride Tablet 2mg
	Composition	Each Film Coated Tablet Contains: Glimepiride…2mg
	Diary No. Date of R& I & fee	Dy No. 13862: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	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	Econid Tablet by Highnoon
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Revise your label claim to uncoated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Tablet Contains: Glimepiride…2mg

Decision: Approved with following label claim:
Each Tablet Contains:
Glimepiride…2mg

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.

102. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Medicos Tablet 100mg
Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
Diary No. Date of R& I & fee	Dy No. 13861: 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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	•

Decision: Approved.

103. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	L Cetam Syrup 120ml
Composition	Each ml Contains: Levetiracetam…100mg
Diary No. Date of R& I & fee	Dy No. 13833: 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 oral solution by Searle
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	•

Decision: Approved.

104. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Mebsrch Tablet 135mg
Composition	Each Film Coated Tablet Contains: Mebeverine HCl…135mg
Diary No. Date of R& I & fee	Dy No. 13855: 07-03-2019

	PKR 20,000/-: 06-03-2019
Pharmacological Group	Anticholinergics
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	Spasfre Tablet of Himont Pharmaceuticals
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Revise your label claim to uncoated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Tablet Contains: Mebeverine HCl…135mg

Decision: Approved with following label claim:

Each Tablet Contains:

Mebeverine HCl…135mg

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.

105.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	Ondra Syrup 50ml
	Composition	Each 5ml Contains: Ondansetron (as hydrochloride dehydrate)..…4mg
	Diary No. Date of R& I & fee	Dy No. 13871: 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	Ondasave oral solution by Medisave
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

106.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	Medipent Tablet 40mg
	Composition	Each Enteric Coated Tablet Contains: Pantoprazole Sodium Sesquihydrate Eq To Pantoprazole…..40mg
	Diary No. Date of R& I & fee	Dy No. 13865: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

107.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**

Brand Name +Dosage Form + Strength	Ptram Tablet 325mg/37.5mg
Composition	Each Film Coated Tablet Contains: Paracetamol…325mg Tramadol as HCl…37.5mg
Diary No. Date of R& I & fee	Dy No. 13858: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Analgesic / Antipyretic
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	(**MHRA** Approved)
Me-too status	Tramal Plus Tablet by Searle
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

108. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Paxit Tablet 20mg
Composition	Each Film Coated Tablet Contains: Paroxetine…20mg
Diary No. Date of R& I & fee	Dy No. 13827: 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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Paroxetine (as HCl)…20mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Paroxetine (as HCl)…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.

109. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Glita Tablet 15mg
Composition	Each Film Coated Tablet Contains: Pioglitazone…15mg
Diary No. Date of R& I & fee	Dy No. 13894: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Thiazolidinediones
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	Piozer Tablet by Hilton
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.

Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Tablet Contains: Pioglitazone (as hydrochloride)…15mg

Decision: Approved with following label claim:

Each Tablet Contains:

Pioglitazone (as hydrochloride)…15mg

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.

110. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Qumed Tablet 200mg
Composition	Each Film Coated Tablet Contains: Quetiapine …200mg
Diary No. Date of R& I & fee	Dy No. 13831: 07-03-2019 PKR 20,000/-: 06-03-2019
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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Quetiapine as Fumarate…200mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:

Quetiapine as Fumarate…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.

111. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Solinate Tablet 5mg
Composition	Each Film Coated Tablet Contains: Solifenacin Succinate..…5mg
Diary No. Date of R& I & fee	Dy No. 13885: 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	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

112. Name and address of manufacturer / Applicant	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
Brand Name +Dosage Form + Strength	Tina Tablet 125mg
Composition	Each Film Coated Tablet Contains: Terbinafine HCl…125mg

Diary No. Date of R& I & fee	Dy No. 13877: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antifungal
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	LAMISIL tablet TGA Australia Approved
Me-too status	Terbitec Tablet by Fynk Pharma
GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
Remarks of the Evaluator[3].	• Revise your label claim to uncoated tablet as per the innovator's product as under along with submission of 7,500/- fee: Each Tablet Contains: Terbinafine HCl…125mg

Decision: Approved with following label claim:

Each Tablet Contains:
Terbinafine HCl…125mg

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.

113.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	Tramic Capsule 500mg
	Composition	Each Capsule Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 13815: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications but available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy Approved
	Me-too status	Btrol Capsule by Bosch pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved with JP specifications

114.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Valtrax 250mg Capsule
	Composition	Each Capsule Contains: Tranexamic Acid…250mg
	Diary No. Date of R& I & fee	Dy No. 13750: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications 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	Btrol Capsule by Bosch pharma
	GMP status	The has submitted copy of GMP certificate based on inspection dated 10-09-2020.
	Remarks of the Evaluator[3].	•

Decision: Approved with JP specifications.

115.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals 124/A Industrial Triangle, Kahuta Road Islamabad**

Brand Name +Dosage Form + Strength	Valtrax 500mg Capsule
Composition	Each Capsule Contains: Tranexamic Acid…500mg
Diary No. Date of R& I & fee	Dy No. 13749: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antifibrinolytics
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications but available in JP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	AIFA Italy Approved
Me-too status	Btrol Capsule by Bosch pharma
GMP status	The has submitted copy of GMP certificate based on inspection dated 10-09-2020.
Remarks of the Evaluator[3].	•

Decision: Approved with JP specifications.

116. Name and address of manufacturer / Applicant	**M/s Valor Pharmaceuticals 124/A Industrial Triangle, Kahuta Road Islamabad**
Brand Name +Dosage Form + Strength	Bonefine 200,000 IU Capsule
Composition	Each Soft Gelatin Capsule Contains: Vitamin D3…200,000 IU
Diary No. Date of R& I & fee	Dy No. 13741: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	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	Could not be confirmed
GMP status	The has submitted copy of GMP certificate based on inspection dated 10-09-2020.
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.**

117. Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Lecitam Tablet 250mg
Composition	Each Capsule Contains: Levetiracetam…250mg
Diary No. Date of R& I & fee	Dy No. 14249: 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	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.

Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Levetiracetam…250mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Levetiracetam…250mg

- **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.**

118.

Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Lecitam Tablet 500mg
Composition	Each Capsule Contains: Levetiracetam…500mg
Diary No. Date of R& I & fee	Dy No. 14248: 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	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Levetiracetam…500mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Levetiracetam…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.**

119.

Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Lecitam Tablet 750mg
Composition	Each Capsule Contains: Levetiracetam…750mg
Diary No. Date of R& I & fee	Dy No. 14247: 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	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Levetiracetam…750mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Levetiracetam…750mg

- **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.**

120. Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Lecitam Syrup 100mg/ml
Composition	Each Capsule Contains: Levetiracetam…100mg
Diary No. Date of R& I & fee	Dy No. 14246: 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 oral solution by Searle
GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to syrup and label claim as per the innovator's product as follow along with submission of full fee of registration: Each ml Contains: Levetiracetam…100mg

Decision: Approved with following label claim:

Each ml Contains:
Levetiracetam…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.**

121. Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Curig 40mg Capsule
Composition	Each Capsule Contains: Febuxostat…40mg
Diary No. Date of R& I & fee	Dy No. 14216: 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 is granted GMP certificate based on inspection conducted on 30-5-2019.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Febuxostat…40mg

Decision: Approved with innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Febuxostat…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.**

122. Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Curig 80mg Capsule
Composition	Each Capsule Contains: Febuxostat…80mg
Diary No. Date of R& I & fee	Dy No. 14215: 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 is granted GMP certificate based on inspection conducted on 30-5-2019.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Febuxostat…80mg

Decision: Approved with innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Febuxostat…80mg

- **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.**

123. Name and address of manufacturer / Applicant	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Olmitan AM 5/20 mg Tablets
Composition	Each Capsule Contains: Amlodipine…5mg Olmesartan Medoxomil…20mg
Diary No. Date of R& I & fee	Dy No. 14225: 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 is granted GMP certificate based on inspection conducted on 30-5-2019.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…20mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Amlodipine as Besylate…5mg
Olmesartan Medoxomil…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.**

124.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan AM 5/40mg Capsule
	Composition	Each Capsule Contains: Amlodipine…5mg Olmesartan Medoximil…40mg
	Diary No. Date of R& I & fee	Dy No. 14224: 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 is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…40mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Amlodipine as Besylate…5mg
Olmesartan Medoxomil…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.**

125.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan AM 10/20mg Capsule
	Composition	Each Capsule Contains: Amlodipine…10mg Olmesartan Medoximil…20mg
	Diary No. Date of R& I & fee	Dy No. 14223: 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 is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Olmesartan Medoxomil…20mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Amlodipine as Besylate…10mg
Olmesartan Medoxomil…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 Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan AM 10/40mg Capsule
	Composition	Each Capsule Contains: Amlodipine…10mg Olmesartan Medoximil…40mg
	Diary No. Date of R& I & fee	Dy No. 14222: 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 is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your formulation to tablet and label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg

Olmesartan Medoxomil…40mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Amlodipine as Besylate…10mg
Olmesartan Medoxomil…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.**

127.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Lemox 40mg Tablet
	Composition	Each Tablet Contains: Olmesartan Medoxomil…40mg
	Diary No. Date of R& I & fee	Dy No. 16333: 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	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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Olmesartan Medoxomil…40mg
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.

128.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Tristron 8mg/4ml Injection
	Composition	Each 4ml ampoule Contains: Ondansetron (as hydrochloride dehydrate).…8mg
	Diary No. Date of R& I & fee	Dy No. 16365: 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	Adhon Injection by Ameer & Adnan
	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.

129.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Tristron 4mg/2ml Injection
	Composition	Each 2ml ampoule Contains: Ondansetron (as hydrochloride dehydrate).…4mg

Diary No. Date of R& I & fee	Dy No. 16354: 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	Adhon Injection by Ameer & Adnan
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.

130. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Brouti 40mg Tablet
Composition	Each Tablet Contains: Otilonium Bromide…40mg
Diary No. Date of R& I & fee	Dy No. 16075: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Anticholinergic, quaternary ammonium compounds
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.	(Spain Approved)
Me-too status	Spasmomen tablet 40mg of Pharmatech
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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Otilonium Bromide…40mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Otilonium Bromide…40mg
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.

131. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Seizine 300mg Tablet
Composition	Each Tablet Contains: Oxcarbazepine …300mg
Diary No. Date of R& I & fee	Dy No. 16097: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antiepileptic
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	Neutrozep Tablet by Neutro 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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Oxcarbazepine …300mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Oxcarbazepine …300mg
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.

132.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Seizine 600mg Tablet
	Composition	Each Tablet Contains: Oxcarbazepine …600mg
	Diary No. Date of R& I & fee	Dy No. 16093: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiepileptic
	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	Neutrozep Tablet by Neutro 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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Oxcarbazepine …600mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Oxcarbazepine …600mg
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.

133.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Spasm Go 40mg/4ml Injection
	Composition	Each 4ml ampoule Contains: Phloroglucinol Dihydrate..…40mg Trimethylphloroglucinol…….0.04mg
	Diary No. Date of R& I & fee	Dy No. 16096: 07-03-2019 PKR 20,000/-: 06-03-2019
	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, solution for injection in ampoule ANSM France Approved
	Me-too status	Phlonol Injection by Wimits 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.

134.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Spasm Go Tablet 80mg
	Composition	Each Tablet Contains: Phloroglucinol Hydrate…80mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Dy No. 16094: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Sugar Coated Tablet Contains: Phloroglucinol Hydrate…80mg Trimethylphloroglucinol…80mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Sugar Coated Tablet Contains:
Phloroglucinol Hydrate…80mg
Trimethylphloroglucinol…80mg
Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

135. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Cetarac 400mg Tablet
Composition	Each Tablet Contains: Piracetam…400mg
Diary No. Date of R& I & fee	Dy No. 16349: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	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.	ANSM France Approved
Me-too status	Nootropil Tablet by M/s GSK
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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Piracetam…400mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Piracetam…400mg
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.

136. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Cetarac 1000mg/5ml Oral Solution
Composition	Each 5ml Contains: Piracetam……1000mg
Diary No. Date of R& I & fee	Dy No. 16349: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	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.	ANSM France Approved
Me-too status	Nootropil Oral solution by M/s GSK
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.

137.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Hapiface 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…100mg
	Diary No. Date of R& I & fee	Dy No. 16061: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

138.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Hapiface 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…25mg
	Diary No. Date of R& I & fee	Dy No. 16060: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

139.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Rabzolin 20mg Tablet
	Composition	Each Tablet Contains: Rabeprazole Sodium…20mg
	Diary No. Date of R& I & fee	Dy No. 16076: 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 11-01-2021.
	Remarks of the Evaluator[3].	• Reference product is available as delayed release tablet while you have applied for plain tablet. Revise your label claim as per the innovator's product as under along with submission of full fee of registration: 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.

140.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Rifinix 550mg Tablet
	Composition	Each Tablet Contains: Rifaximin…550mg
	Diary No. Date of R& I & fee	Dy No. 16084: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	Valaximin Tablet by Valor 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 to film coated tablet along with submission of 7,500 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.

141.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Faxet 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy No. 16325: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	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	Faxet 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R& I & fee	Dy No. 16342: 07-03-2019 PKR 20,000/-: 06-03-2019
	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	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	Fencate 5mg Tablet
Composition	Each Tablet Contains: Solifenacin Succinate…5mg
Diary No. Date of R& I & fee	Dy No. 16331: 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	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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Solifenacin Succinate…5mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Solifenacin Succinate…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	Fencate 10mg Tablet
Composition	Each Tablet Contains: Solifenacin Succinate…10mg
Diary No. Date of R& I & fee	Dy No. 16323: 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	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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Solifenacin Succinate…10mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Solifenacin Succinate…10mg

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	Terfin 1% w/w topical lotion
	Composition	Each ml Contains: Terbinafine HCl…1%W/W
	Diary No. Date of R& I & fee	Dy No. 16362: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil® OnceTM 1% cutaneous solution MHRA Approved
	Me-too status	Terbisil Lotion by Saffron
	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.

146.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Fintix B 1% Cream
	Composition	Each gram of cream Contains: Terbinafine HCl…1%
	Diary No. Date of R& I & fee	Dy No. 16058: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Terbin Cream by Seatle
	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.

147.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Fintix B 1% Gel
	Composition	Each gram of gel Contains: Terbinafine HCl…1%
	Diary No. Date of R& I & fee	Dy No. 16088: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	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	Lamisil Derm Gel by GSK
	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 as per the innovator's product along with submission of full fee of registration as per following: Each gram of gel Contains: Terbinafine…1%

Decision: Approved with Innovator's specifications and with following label claim:
Each gram of gel Contains:
Terbinafine…1%
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.

148.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Terfin 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine HCl…125mg
	Diary No. Date of R& I & fee	Dy No. 16361: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL tablet TGA Australia Approved
	Me-too status	Terbitec Tablet by Fynk 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.

149.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Fintix B 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine HCl…250mg
	Diary No. Date of R& I & fee	Dy No. 16087: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL tablet TGA Australia Approved
	Me-too status	Terbitec Tablet by Fynk 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.

150.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Thiospasm 4mg tablet
	Composition	Each Tablet Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 16100: 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 11-01-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

151.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Thiospasm 4mg/2ml Injection
	Composition	Each 2ml ampoule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 16348: 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/2 ml, solution for injection (IM) in ampoule ANSM France Approved
	Me-too status	Chicowel Injection 4mg/2ml by Welmark
	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.

152.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Primot 50mg Tablet
	Composition	Each Tablet Contains: Topiramate…50mg
	Diary No. Date of R& I & fee	Dy No. 16326: 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	Hitop Tablet by Hilton
	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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Topiramate…50mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Topiramate…50mg
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	Tramacute A 100mg ER Tablet
	Composition	Each Tablet Contains: Tramadol HCl…100mg
	Diary No. Date of R& I & fee	Dy No. 16071: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesic
	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	Tonoflex SR Tablet by Sami
	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 as per the innovator's product as under along with submission of full fee of registration: Each Sustained Release Tablet Contains: Tramadol HCl …100mg

Decision: Approved with following label claim:
Each Sustained Release Tablet Contains:
Tramadol HCl …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.

154. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Eprise 50mg Tablet
Composition	Each Tablet Contains: Eperisone HCl…50mg
Diary No. Date of R& I & fee	Dy No. 16355: 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.	Eperisone Hydrochloride Tablets 50mg "TCK" PMDA Japan Approved (Sugar coated tablet)
Me-too status	Eprisa Tablet by Fynk 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 to sugar coated tablet as per the innovator's product as under along with submission of 7,500/- fee: Each Sugar coated Tablet Contains: Eperisone HCl…50mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Sugar coated Tablet Contains:
Eperisone HCl…50mg
Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to sugar 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 Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
Brand Name +Dosage Form + Strength	Davical 667mg Tablet
Composition	Each Tablet Contains: Calcium Acetate…667mg
Diary No. Date of R& I & fee	Dy No. 16458: 07-03-2019 PKR 20,000/-: 04-03-2019
Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia
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	Elephos Tablet by Genome
GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
Remarks of the Evaluator[3].	• Evidence of approval of applied formulation (as uncoated tablet) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting • Evidence of atomic absorption spectroscopy, which is required for dissolution testing of the applied product.

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:

Calcium Acetate…667mg

- **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.**
- **Registration letter will be issued after submission of evidence of atomic absorption spectrophotometer along with its IQ, OQ and PQ.**

156.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad**
	Brand Name +Dosage Form + Strength	Amino-L Sachet
	Composition	Each Sachet Contains: L-Ornithine L-Aspartate…3g
	Diary No. Date of R& I & fee	Dy No. 16456: 07-03-2019 PKR 20,000/-: 04-03-2019
	Pharmacological Group	Hepatoprotective
	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 3g Granules by **Austria** Approved
	Me-too status	Hepa Merz Sachet by Brookes
	GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
	Remarks of the Evaluator[3].	• Firm has submitted copy of letter of renewal of DML dated 20-11-2015 specifying Sachet (General) Section. • Firm has also submitted copy of GMP certificate dated 15-02-2022 issued on the basis of inspection dated 02-02-2022 specifying Sachet (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.**

157.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad**
	Brand Name +Dosage Form + Strength	Zinex 20mg Tablet
	Composition	Each Dispersible Tablet Contains: Zinc Sulphate Monohydrate eq. To Elemental Zinc…20mg
	Diary No. Date of R& I & fee	Dy No. 16457: 07-03-2019 PKR 20,000/-: 04-03-2019
	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.	WHO PQ formulation
	Me-too status	Zihe Tablet by Dynatis Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted 02-02-2022.
	Remarks of the Evaluator[3].	•

Decision: Approved.

158.	**Name and address of manufacturer / Applicant**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore**
	Brand Name +Dosage Form + Strength	Ceften 90mg/5ml Suspension
	Composition	Each 5ml Contains: Ceftibuten Dihydrate Eq. To Ceftibuten…90mg
	Diary No. Date of R& I & fee	Dy No. 13925: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Cephalosporin
	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.	CEDAX (90mg/5ml) for suspension USFDA approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
Me-too status	Neutosef Dry Suspension 90mg/5ml by Neutro Pharma
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 approval letter from Licensing Division

Decision: Deferred for following submissions:

- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**
- **GMP inspection report conducted within a period of last 3 years.**

159. Name and address of manufacturer / Applicant	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Formacid 250mg Tablet
Composition	Each Tablet Contains: Metformin HCl…250mg
Diary No. Date of R& I & fee	Dy No. 17017: 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	Glucophage Tablet by Martin Dow
GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends 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 evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

160. Name and address of manufacturer / Applicant	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Formacid 500mg Tablet
Composition	Each Tablet Contains: Metformin HCl…500mg
Diary No. Date of R& I & fee	Dy No. 17018: 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 has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Metformin HCl…500mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:

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.

161.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Formacid 850mg Tablet
	Composition	Each Tablet Contains: Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy No. 17019: 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 has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
	Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Metformin HCl…850mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Metformin HCl…850mg
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.

162.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Formacid 1g Tablet
	Composition	Each Tablet Contains: Metformin HCl…1g
	Diary No. Date of R& I & fee	Dy No. 17020: 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 has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
	Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Metformin HCl…1g

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Metformin HCl…….1g
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.

163.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**

Brand Name +Dosage Form + Strength	Galpin 25mg Tablet
Composition	Each Tablet Contains: Sitagliptin As Phospate Monohydrate…25mg
Diary No. Date of R& I & fee	Dy No. 17014: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
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	Tagip tablets by Highnoon
GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate…25mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Sitagliptin as Phospate Monohydrate…25mg
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.

164. Name and address of manufacturer / Applicant	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Galpin 50mg Tablet
Composition	Each Tablet Contains: Sitagliptin As Phospate Monohydrate…50mg
Diary No. Date of R& I & fee	Dy No. 17015: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
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	Tagip tablets by Highnoon
GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate…50mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Sitagliptin as Phospate Monohydrate…50mg
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.

165. Name and address of manufacturer / Applicant	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Galpin 100mg Tablet
Composition	Each Tablet Contains: Sitagliptin As Phospate Monohydrate…100mg
Diary No. Date of R& I & fee	Dy No. 17016: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic

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	Tagip tablets by Highnoon
GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate…100mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Sitagliptin as Phospate Monohydrate…100mg
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.

166. Name and address of manufacturer / Applicant	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Galformin 50/500mg Tablet
Composition	Each Tablet Contains: Sitagliptin as Phospate Monohydrate…50mg Metformin HCl…500mg
Diary No. Date of R& I & fee	Dy No. 17012: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
Type of Form	Form 5
Finished Product Specification	Innovator's specs
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 has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: 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
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.

167. Name and address of manufacturer / Applicant	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Galformin 50/1000mg Tablet
Composition	Each Tablet Contains: Sitagliptin as Phospate Monohydrate…50mg Metformin HCl…1000mg
Diary No. Date of R& I & fee	Dy No. 17013: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
Type of Form	Form 5
Finished Product Specification	Innovator's specs
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 has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
Remarks of the Evaluator[3].	• Firm has revised the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: 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
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.

168. Name and address of manufacturer / Applicant	**M/s Cibex (Pvt) Ltd. F-405, S.I.T.E, Karachi**
Brand Name +Dosage Form + Strength	Dydis 10mg Tablet
Composition	Each Tablet Contains: Domperidone Maleate Eq To Domperidone…10mg
Diary No. Date of R& I & fee	Dy No. 15000: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Propulsives
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	Domel Tablet by Barrett Hodgson
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.

169. Name and address of manufacturer / Applicant	**M/s Cibex (Pvt) Ltd. F-405, S.I.T.E, Karachi**
Brand Name +Dosage Form + Strength	Dydis 5mg/5ml Suspension
Composition	Each 5ml Contains: Domperidone…5mg
Diary No. Date of R& I & fee	Dy No. 14999: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Propulsives
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	Domel Suspension by Barrett Hodgson
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.

170. Name and address of manufacturer / Applicant	**M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan**

Brand Name +Dosage Form + Strength	Bloser 100mg Tablet
Composition	Each Tablet Contains: Sertraline as HCl…100mg
Diary No. Date of R& I & fee	Dy No. 16186: 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.	MHRA Approved
Me-too status	Zoloft Tablet by Pfizer
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 21-06-2022.
Remarks of the Evaluator[3].	• Firm has revise the label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Sertraline (as HCl)…100mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Sertraline (as HCl)…100mg

171.	**Name and address of manufacturer / Applicant**	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Amlorex 5mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…5mg
	Diary No. Date of R& I & fee	Dy No. 16951: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	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.	MHRA Approved
	Me-too status	Norvasc Tablet by Pfizer
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

172.	**Name and address of manufacturer / Applicant**	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Amlorex 10mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…10mg
	Diary No. Date of R& I & fee	Dy No. 16952: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	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.	MHRA Approved
	Me-too status	Norvasc Tablet by Pfizer
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
	Remarks of the Evaluator[3].	•

Decision: Approved.

173.	**Name and address of manufacturer / Applicant**	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Biocard 5/160 mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 16957: 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
	Remarks of the Evaluator[3].	• Firm has revised label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: 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

174.	**Name and address of manufacturer / Applicant**	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Biocard Plus 10/160 mg Tablet
	Composition	Each Tablet Contains: Amlodipine as Besylate…10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 16958: 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	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
	Remarks of the Evaluator[3].	• Firm has revised label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: 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…5mg
Valsartan…160mg

175.	**Name and address of manufacturer / Applicant**	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Gabarex 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Dy No. 16953: 07-03-2019

	PKR 20,000/-: 07-03-2019
Pharmacological Group	Anticonvulsant
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications while available in BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA approved
Me-too status	Gabica Capsule by Getz
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with BP 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.**

176. Name and address of manufacturer / Applicant	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
Brand Name +Dosage Form + Strength	Gabarex 75mg Capsule
Composition	Each Capsule Contains: Pregabalin…75mg
Diary No. Date of R& I & fee	Dy No. 16954: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Anticonvulsant
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications while available in BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA approved
Me-too status	Gabica Capsule by Getz
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
Remarks of the Evaluator[3].	•

Decision: Approved with BP 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.**

177. Name and address of manufacturer / Applicant	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
Brand Name +Dosage Form + Strength	Sitamin-M Plus Tablet
Composition	Each Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCl…500mg
Diary No. Date of R& I & fee	Dy No. 16955: 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	Treivamet Tablet by Getz
GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
Remarks of the Evaluator[3].	• Firm has revised label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: 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

178.	**Name and address of manufacturer / Applicant**	**M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Sitamin-M Plus Tablet
	Composition	Each Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 16956: 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	Treivamet Tablet by Getz
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 09-12-2021.
	Remarks of the Evaluator[3].	• Firm has revised label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: 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

179.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	Defsirox 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Deferasirox…500mg
	Diary No. Date of R& I & fee	Dy No. 16318: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Iron chelating 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.	Could not be confirmed, available as dispersible tablet in MHRA
	Me-too status	Available as dispersible tablet
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	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, since the applied formulation is available as dispersible tablet in RRAs.

Decision: Approved with Innovator's specifications and with following label claim:
Each Dispersible Tablet Contains:
Deferasirox…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.

180.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.**
	Brand Name +Dosage Form + Strength	E-Cital 20mg Tablet
	Composition	Each Film Coated Tablet Contains:

	Escitalopram Oxalate…20mg
Diary No. Date of R& I & fee	Dy No. 16316: 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	Citanew Tablet by Hilton
GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
Remarks of the Evaluator[3].	• Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Escitalopram as Oxalate…20mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Escitalopram as Oxalate…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.

181. Name and address of manufacturer / Applicant	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.**
Brand Name +Dosage Form + Strength	Thiolaksent 4mg/2ml Injection
Composition	Each 2ml ampoule contains: Thiocolchicoside…4mg
Diary No. Date of R& I & fee	Dy No. 16322: 07-03-2019 PKR 20,000/-: 07-03-2019
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/2 ml, solution for injection (IM) in ampoule ANSM France Approved
Me-too status	Chicowel Injection 4mg/2ml by Welmark
GMP status	
Remarks of the Evaluator[3].	•

Decision: Approved with Innovator's specifications.

182. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Dulet Capsule 30mg
Composition	Each Capsule Contains: Duloxetine as HCl…30mg
Diary No. Date of R& I & fee	Dy No. 14675: 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 as per the innovator's product as follow along with submission of full fee of registration:
  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.**

183. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Dulet Capsule 60mg
Composition	Each Capsule Contains: Duloxetine as HCl…60mg
Diary No. Date of R& I & fee	Dy No. 14676: 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 as per the innovator's product as follow along with submission of full fee of registration: 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.**

184. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Excite Tablet 5mg
Composition	Each Tablet Contains: Escitalopram …5mg
Diary No. Date of R& I & fee	Dy No. 14679: 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	Citanew Tablet by Hilton
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Escitalopram as Oxalate…5mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Escitalopram as Oxalate…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.**

185. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Excite Tablet 10mg
Composition	Each Tablet Contains: Escitalopram …10mg
Diary No. Date of R& I & fee	Dy No. 14680: 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	Citanew Tablet by Hilton
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Escitalopram as Oxalate…10mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Escitalopram as Oxalate…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.**

186. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Excite Tablet 20mg
Composition	Each Tablet Contains: Escitalopram …20mg
Diary No. Date of R& I & fee	Dy No. 14681: 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	Citanew Tablet by Hilton
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Escitalopram as Oxalate…20mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Escitalopram as Oxalate…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.**

187. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Xopride Tablet 1mg
Composition	Each Tablet Contains: Glimepride…1mg
Diary No. Date of R& I & fee	Dy No. 14825: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
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	Econid Tablet by Highnoon
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.**

188. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Xopride Tablet 2mg
Composition	Each Tablet Contains: Glimepride…2mg
Diary No. Date of R& I & fee	Dy No. 14826: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antidiabetic
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	Econid Tablet by Highnoon
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.

189.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Xopride Tablet 3mg
	Composition	Each Tablet Contains: Glimepride…3mg
	Diary No. Date of R& I & fee	Dy No. 14662: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	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	Econid Tablet by Highnoon
	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.

190.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Xopride Tablet 4mg
	Composition	Each Tablet Contains: Glimepride…4mg
	Diary No. Date of R& I & fee	Dy No. 14663: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	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	Econid Tablet by Highnoon
	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.

191.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Gliformin 1mg/500mg Tablet
	Composition	Each Tablet Contains: Glimepride…1mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 14612: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Sulfonylureas + Biguanides
	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	Getformin Tablet by Getz
	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:

- **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**
- **Updated GMP inspection report conducted within aperiod of last 3 years.**

192. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Gliformin 2mg/500mg Tablet
Composition	Each Tablet Contains: Glimepride…2mg Metformin…500mg
Diary No. Date of R& I & fee	Dy No. 14813: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Sulfonylureas + Biguanides
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	Getformin Tablet by Getz
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:

- **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**
- **Updated GMP inspection report conducted within aperiod of last 3 years.**

193. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Motrig 50mg Tablet
Composition	Each Tablet Contains: Lamotrigine…50mg
Diary No. Date of R& I & fee	Dy No. 14690: 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	Lamictal Tablet by GSK
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.

194. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Motrig 100mg Tablet
Composition	Each Tablet Contains: Lamotrigine…100mg
Diary No. Date of R& I & fee	Dy No. 14691: 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	Lamictal Tablet by GSK
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.

195. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Zolan Capsule 30mg
Composition	Each Capsule Contains: Lansoprazole…30mg
Diary No. Date of R& I & fee	Dy No. 14686: 07-03-2019 PKR 20,000/-: 06-03-2019
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	Lanzol Capsule by Pharmatec
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 follow along with submission of full fee of registration: Each Capsule Contains: Lansoprazole (as enteric Coated Pellets)..…30mg

Decision: Approved with following label claim:

Each Capsule Contains:
Lansoprazole (as enteric Coated Pellets)..…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.**

196. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Glucomet Tablet 500mg
Composition	Each Tablet Contains: Metformin HCl…500mg
Diary No. Date of R& I & fee	Dy No. 14664: 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	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Metformin HCl…500mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
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.**
- **Registration letter will be issued after submission of updated GMP inspection report by the firm.**

197. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Glucomet Tablet 850mg
Composition	Each Tablet Contains: Metformin HCl…850mg
Diary No. Date of R& I & fee	Dy No. 14665: 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	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Metformin HCl…850mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Metformin HCl…850mg

- **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.**
- **Registration letter will be issued after submission of updated GMP inspection report by the firm.**

198. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Nebiv Tablet 2.5mg
Composition	Each Tablet Contains: Nebivolol as HCl…2.5mg
Diary No. Date of R& I & fee	Dy No. 14819: 07-03-2019 PKR 20,000/-: 06-03-2019
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.

199.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Nebiv Tablet 5mg
	Composition	Each Tablet Contains: Nebivolol as HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 14820: 07-03-2019 PKR 20,000/-: 06-03-2019
	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.

200.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Nebiv Tablet 10mg
	Composition	Each Tablet Contains: Nebivolol as HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 14821: 07-03-2019 PKR 20,000/-: 06-03-2019
	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.

201.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
	Brand Name +Dosage Form + Strength	Zolax Capsule 40mg
	Composition	Each Capsule Contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 14659: 07-03-2019 PKR 20,000/-: 06-03-2019
	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 as per the innovator's product as follow along with submission of full fee of registration: 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.**

202. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Pregab Capsule 50mg
Composition	Each Capsule Contains: Pregabalin…50mg
Diary No. Date of R& I & fee	Dy No. 14677: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Anticonvulsant
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications while available in BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA approved
Me-too status	Gabica Capsule by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

Decision: Approved with BP 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.**

203. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Pregab Capsule 75mg
Composition	Each Capsule Contains: Pregabalin…75mg
Diary No. Date of R& I & fee	Dy No. 14678: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Anticonvulsant
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications while available in BP
Pack size & Demanded Price	As per SRO

Approval status of product in Reference Regulatory Authorities.	USFDA approved
Me-too status	Gabica Capsule by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

Decision: Approved with BP 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.**

204. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Pregab Capsule 150mg
Composition	Each Capsule Contains: Pregabalin…150mg
Diary No. Date of R& I & fee	Dy No. 14687: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Anticonvulsant
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications while available in BP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA approved
Me-too status	Gabica Capsule by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

Decision: Approved with BP 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.**

205. Name and address of manufacturer / Applicant	**M/s Baxter Pharmaceuticals A-1/A, Scheme No. 33, Phase-1, S.I.T.E, Super Highway, Karachi.**
Brand Name +Dosage Form + Strength	Valart Tablet 80mg
Composition	Each Tablet Contains: Valsartan…80mg
Diary No. Date of R& I & fee	Dy No. 14811: 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	Diovan Tablet by Novartis
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim to film coated tablet as per the innovator's product as under along with submission of 7500/- fee: Each Film Coated Tablet Contains: Valsartan…80mg

Decision: Approved with following label claim:
Each Film Coated Tablet Contains:
Valsartan…80mg

- **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.**
- **Registration letter will be issued after submission of updated GMP inspection report by the firm.**

206. Name and address of manufacturer / Applicant	**M/s Aventek Pharmaceuticals Pvt Ltd 44-C, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Avesulzone 2g Injection
Composition	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
Diary No. Date of R& I & fee	Dy No. 16371: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Cephalosporin
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specifications while the product monograph is 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 Injection by High-Q
GMP status	
Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division

Decision: Deferred for following:

- **Reference of finished product specifications.**
- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

207. Name and address of manufacturer / Applicant	**M/s Aventek Pharmaceuticals Pvt Ltd 44-C, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Avetron 2g Injection IV
Composition	Each Vial Contains: Ceftriaxone Sodium…2g
Diary No. Date of R& I & fee	Dy No. 16372: 07-03-2019 PKR 20,000/-: 06-03-2019
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.	MHRA Approved
Me-too status	Oxidil Injection by Sami
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Vial Contains: Ceftriaxone (as sodium)…2g

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

208. Name and address of manufacturer / Applicant	**M/s Aventek Pharmaceuticals Pvt Ltd 44-C, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Spas tablet 80/80mg

Composition	Each Sugar Coated Tablet Contains: Phloroglucinol Hydrate…80mg Trimethylphloroglucinol…80mg
Diary No. Date of R& I & fee	Dy No. 16373: 07-03-2019 PKR 20,000/-: 06-03-2019
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	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

Decision: Approved with Innovator' 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.**

209. Name and address of manufacturer / Applicant	**M/s Aventek Pharmaceuticals Pvt Ltd 44-C, Sunder Industrial Estate, Lahore**
Brand Name +Dosage Form + Strength	Lipton Plus Tablet 50/500mg
Composition	Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate…50mg Metformin HCl…500mg
Diary No. Date of R& I & fee	Dy No. 16375: 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	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' 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.**

210. 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	B Histine 16mg Tablet
Composition	Each Tablet Contains: Betahistine Dihydrochloride…16mg
Diary No. Date of R& I & fee	Dy No. 13327: 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	
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.**

211.	**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	Letroze 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy No. 13371: 07-03-2019 PKR 20,000/-: 07-03-2019
	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	
	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.

212.	**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	Arractam 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 13357: 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	Lumark Tablet by Searle
	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.

213.	**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	Nebilol 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Nebivolol as HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 13339: 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' 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.**

214. 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	Rosuvastatin 10mg Tablet
Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium eq to Rosuvastatin…10mg
Diary No. Date of R& I & fee	Dy No. 13317: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	HMG CoA reductase 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	Crestat Tablet by CCL
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.

215. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Citinate 500mg Tablet
Composition	Each Tablet Contains: Citicoline As Sodium…500mg
Diary No. Date of R& I & fee	Dy No. 16352: 07-03-2019 PKR 20,000/-: 06-03-2019
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.	Could not be confirmed
Me-too status	Cercolin Tablet by The Schazoo Pharmaceutical
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.

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.

216. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Citinate 250mg/ml Injection
Composition	Each ml Contains: Citicoline As Sodium…1000mg
Diary No. Date of R& I & fee	Dy No. 16353: 07-03-2019 PKR 20,000/-: 06-03-2019
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	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 (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.**

217.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Ancolan 1% Topical Lotion
	Composition	Each ml Contains: Clindamycin (as phosphate).....1%
	Diary No. Date of R& I & fee	Dy No. 16068: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	Antibiotics
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lindagen Lotion by Biogen
	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.

218.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Clopron 0.05% Topical Lotion
	Composition	Each ml Contains: Clobetasol Propionate……0.05%
	Diary No. Date of R& I & fee	Dy No. 16069: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	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	Maxivate lotion by Maxitech
	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.

219.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Clopron 0.05% cream
	Composition	Each gram of cream Contains: Clobetasol Propionate……0.05%
	Diary No. Date of R& I & fee	Dy No. 16057: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	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	Maxivate cream by Maxitech
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.

220. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Trignozil 1% Topical Lotion
Composition	Each ml Contains: Clotrimazole…1%
Diary No. Date of R& I & fee	Dy No. 16360: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antifungals for topical 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	Canix 1% Lotion by Crystolite
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.

221. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Diazepam Injection 10mg/2ml
Composition	Each 2ml ampoule Contains: Diazepam…10mg
Diary No. Date of R& I & fee	Dy No. 16343: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Benzodiazepine 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	Valium Injection by Martin Dow
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.

222. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Drolec V 40mg Tablet
Composition	Each Tablet Contains: Drotaverine HCl…40mg
Diary No. Date of R& I & fee	Dy No. 16091: 07-03-2019 PKR 20,000/-: 06-03-2019
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.	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Lithuania & Latvia (both as un-coated and coated tablets).

Me-too status	No-Spa Tablet by Sanofi Aventis
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.
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.

223. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Drolec V 80mg Tablet
Composition	Each Tablet Contains: Drotaverine HCl…80mg
Diary No. Date of R& I & fee	Dy No. 16090: 07-03-2019 PKR 20,000/-: 06-03-2019
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.	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Lithuania & Latvia (both as un-coated and coated tablets).
Me-too status	No-Spa Tablet by Sanofi Aventis
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.
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.

224. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Bonfix 150mg Tablet
Composition	Each Tablet Contains: Ibandronate Sodium…150mg
Diary No. Date of R& I & fee	Dy No. 16358: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Bisphosphonates
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	Ibnate Tablets by Genix 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 as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Ibandronic acid (as sodium monohydrate).…150mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Ibandronic acid (as sodium monohydrate).…150mg

- **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 Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Aconoion 0.05% Gel
Composition	Each gm of gel Contains: Isotretinoin …0.05%

Diary No. Date of R& I & fee	Dy No. 16092: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Retinoids for treatment of acne
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	Acutin Gel by Linta 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.

226. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Itogasta 50mg Tablet
Composition	Each Tablet Contains: Itopride HCl…50mg
Diary No. Date of R& I & fee	Dy No. 16356: 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	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
Remarks of the Evaluator[3].	• Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Itopride HCl……50mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Itopride HCl……50mg
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.

227. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Conket 200mg Tablet
Composition	Each Tablet Contains: Ketoconazole…200mg
Diary No. Date of R& I & fee	Dy No. 16336: 07-03-2019 PKR 20,000/-: 06-03-2019
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	Danzap Tablet by Hilton
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.

228. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**

Brand Name +Dosage Form + Strength	Conket 2% Topical Solution
Composition	Each ml Contains: Ketoconazole…2%
Diary No. Date of R& I & fee	Dy No. 16089: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Imidazole derivatives
Type of Form	Form 5
Finished Product Specification	JP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Ketoconazole Lotion 2% (PMDA Japan Approved)
Me-too status	Kenazole Lotion by Nabiqasim
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.

229. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Lamot 100mg Tablet
Composition	Each Tablet Contains: Lamotrigine…100mg
Diary No. Date of R& I & fee	Dy No. 16345: 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	Lamictal Tablet by GSK
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.

230. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Vulide S 50mg Tablet
Composition	Each Tablet Contains: Levosulpride…50mg
Diary No. Date of R& I & fee	Dy No. 16082: 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.	AIFA Italy approved.
Me-too status	Levide tablet by Swiss 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.
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.

231. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Oxilor 8mg Tablet
Composition	Each Tablet Contains:

	Lornoxicam…8mg
Diary No. Date of R& I & fee	Dy No. 16365: 07-03-2019 PKR 20,000/-: 06-03-2019
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.	Xefo 8mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
Me-too status	Zafon Tablets by Getz
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 to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Lornoxicam…8mg

Decision: Approved with Innovator's specifications and with following label claim:
Each Film Coated Tablet Contains:
Lornoxicam…8mg
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.

232. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Mebrex 135mg Tablet
Composition	Each Tablet Contains: Mebeverine HCl…135mg
Diary No. Date of R& I & fee	Dy No. 16357: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Anticholinergics
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	Spasfre Tablet of Himont Pharmaceuticals
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.

233. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
Brand Name +Dosage Form + Strength	Telzam 10mg Tablet
Composition	Each Tablet Contains: Metolazone…10mg
Diary No. Date of R& I & fee	Dy No. 16079: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Diuretics
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	Neumetoz 10mg Tablet of Neutro 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].	• Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board

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.

234.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Dermason 0.1% Topical Lotion
	Composition	Each ml Contains: Mometasone Furoate…0.1%
	Diary No. Date of R& I & fee	Dy No. 16086: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	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	Mometaval lotion by Valor 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.

235.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Nalbuphine HCl Injection 10mg
	Composition	Each Injection Contains: Nalbuphine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16337: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Morphinan 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.	USFDA Approved
	Me-too status	Nalbin Injection by Global
	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.

- **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.**

236.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-km, Thokar Raiwind Road, Lahore.**
	Brand Name +Dosage Form + Strength	Nalbuphine HCl Injection 20mg
	Composition	Each 1ml ampoule Contains: Nalbuphine Hcl…20mg
	Diary No. Date of R& I & fee	Dy No. 16366: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Morphinan 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.	USFDA Approved
	Me-too status	Nalbin Injection by Global
	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.

- **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.**

237.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Olmecell 5/20 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy No. 16294: 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	
	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.

238.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Olmecell 10/20 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy No. 16293: 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	
	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.

239.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Olmecell 10/40 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Olmesartan Medoxomil…40mg
	Diary No. Date of R& I & fee	Dy No. 16292: 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	
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.

240. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Iroless 250mg Dispersible Tablet
Composition	Each Dispersible Tablet Contains: Deferasirox…250mg
Diary No. Date of R& I & fee	Dy No. 16289: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Iron chelating agents
Type of Form	Form 5
Finished Product Specification	Firm has claimed in-house specifications while product monograph is available in Ph. Eu
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Obsarox Tablet by Aspin
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

Decision: Approved with Ph. Eu 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.**

241. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Iroless 500mg Tablet
Composition	Each Tablet Contains: Deferasirox…500mg
Diary No. Date of R& I & fee	Dy No. 16288: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Iron chelating 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.	Could not be confirmed, available as dispersible tablet in MHRA
Me-too status	Available as dispersible tablet
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, since the applied formulation is available as dispersible tablet in RRAs.

Decision: Approved with Ph. Eu specifications and with following label claim:
Each Dispersible Tablet Contains:
Deferasirox…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.**

242. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**

Brand Name +Dosage Form + Strength	Dios Mec Sachet
Composition	Each Sachet Contains: Dioctahedral Smectite…3gm
Diary No. Date of R& I & fee	Dy No. 16008: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antidiarrhoeal
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.	DIOSMECTITE VIATRIS 3 g, powder for oral suspension in sachet (Available in ANSM France as Diosmectite)
Me-too status	Smecta Sachet by Atco
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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

243. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Astamin 400mg Tablet
Composition	Each Uncoated Tablet Contains: Doxofylline…400mg
Diary No. Date of R& I & fee	Dy No. 16023: 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	Xofi Tablet by Hilton
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.**

244. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Finax 5mg Tablet
Composition	Each Film Coated Tablet Contains: Finasteride…5mg
Diary No. Date of R& I & fee	Dy No. 16290: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Testosterone-5-alpha reductase 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	Genesis Tablet by Ferozesons
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.**

245. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Fumide 40/5 mg tablet
Composition	Each Capsule Contains: Furosemide…40mg Amiloride…5mg
Diary No. Date of R& I & fee	Dy No. 16285: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Diuretics and potassium-sparing agents in combination
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 (as tablet)
Me-too status	Lasoride Tablet by Sanofi Aventis
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Your brand name specifies tablet dosage form while the label claim states that it is a capsule dosage form. Clarification is required in this regard. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Furosemide.…40mg Anhydrous amiloride hydrochloride ….5mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Furosemide.…40mg
Anhydrous amiloride hydrochloride ….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.**

246. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Bonefix 150mg Tablets
Composition	Each Film Coated Tablet Contains: Ibandronic Acid…150mg
Diary No. Date of R& I & fee	Dy No. 16287: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Bisphosphonates
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	Ibnate Tablets by Genix Pharma
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains:

Ibandronic acid (as sodium monohydrate).…150mg

Decision: Approved with Innovator's specifications and with following label claim:

Each Film Coated Tablet Contains:
Ibandronic acid (as sodium monohydrate).…150mg

- **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.**

247. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Ivaro 5mg Tablet
Composition	Each Film Coated Tablet Contains: Ivabradine HCl Eq. To Ivabradine…5mg
Diary No. Date of R& I & fee	Dy No. 16296: 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	
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.**

248. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Ivaro 7.5mg Tablet
Composition	Each Film Coated Tablet Contains: Ivabradine HCl Eq. To Ivabradine…7.5mg
Diary No. Date of R& I & fee	Dy No. 16295: 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	
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.**

249. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Hepacor Sachet
Composition	Each Sachet Contains: L Ornithine-L Aspartate…3g
Diary No. Date of R& I & fee	Dy No. 16001: 07-03-2019

	PKR 20,000/-: 07-03-2019
Pharmacological Group	Hepatoprotective
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 3g Granules by **Austria** Approved
Me-too status	Hepa Merz Sachet by Brookes
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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

250. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Montezan 4mg Sachet
Composition	Each Sachet Contains: Montelukast as Sodium…4mg
Diary No. Date of R& I & fee	Dy No. 16002: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Leukotriene receptor 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	Montiget Sachet by Getz
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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

251. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Reflux Insta 40/1680 mg Sachet
Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
Diary No. Date of R& I & fee	Dy No. 16001: 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.	USFDA
Me-too status	Risek Insta Sachet by Getz
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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

252.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Forlay Sachet
	Composition	Each Sachet Contains: Polyethylene Glycol…13.125g Sodium Chloride…0.3507g Sodium Bicarbonate…0.1785g Potassium Chloride…0.0466g
	Diary No. Date of R& I & fee	Dy No. 16009: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Osmotic laxative
	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.	Movicol 13.8g sachet, powder for oral solution MHRA Approved
	Me-too status	Fasogol Sachet by Faas Pharma
	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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

253.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Carbomax-R Sachet
	Composition	Each Sachet Contains: Pre Cooked Rice Powder…6Gm Sodium Chloride…0.580Gm Sodium Citrate…0.350Gm Potassium Chloride…0.300Gm
	Diary No. Date of R& I & fee	Dy No. 16004: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Electrolytes with carbohydrates
	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.	Dioralyte Relief Blackcurrant Sachets (**MHRA** Approved)
	Me-too status	Peditral-R Sachet by Searle
	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 approval letter from Licensing Division • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Sachet Contains: Pre-Cooked Rice Powder…6gm Sodium Citrate…0.580gm Sodium Chloride…0.350gm Potassium Chloride…0.300gm

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

254. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Sitazan P 50mg Tablet
Composition	Each Film Coated Tablet Contains: Sitagliptin As Phosphate…50mg
Diary No. Date of R& I & fee	Dy No. 16291: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antidiabetic
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	Tagip tablets by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg

Decision: Approved with following label claim:

Each Film Coated Tablet Contains:
Sitagliptin as phosphate monohydrate…50mg

- **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.**

255. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Sitalip DS 50/500 mg Tablet
Composition	Each Film Coated Extended Release Tablet Contains: Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…500mg
Diary No. Date of R& I & fee	Dy No. 16022: 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	Treivamet Tablet by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**

- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

256. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Sitazan XR 50/850 mg Tablet
Composition	Each Film Coated Extended Relase Tablet Contains: Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…850mg
Diary No. Date of R& I & fee	Dy No. 16286: 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	Treivamet Tablet by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

257. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Sitalip DS 50/1000 mg Tablet
Composition	Each Film Coated Extended Release Tablet Contains: Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…1000mg
Diary No. Date of R& I & fee	Dy No. 16021: 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	Treivamet Tablet by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

258.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	U Max Sachets
	Composition	Each Sachet Contains: Sodium Bicarbonate…1.716g Sodium Citrate…0.613g Citric Acid…0.702g Tartaric Acid…0.858g
	Diary No. Date of R& I & fee	Dy No. 16006: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Gastric antacid and urinary alkalizing agent
	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	
	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. • 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

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**
- **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 Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Electomax Sachet
	Composition	Each Sachet Contains: Sodium Chloride…2.6g Trisoidum Citrate Dihydrate…2.9g Potassium Chloride…1.5g Glucose Anhydrous…13.5g
	Diary No. Date of R& I & fee	Dy No. 16007: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Oral Rehydration Salts
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved ORS formulation
	Me-too status	OEM Orange Flavour, Indus Pharma
	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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

260.	**Name and address of manufacturer / Applicant**	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
	Brand Name +Dosage Form + Strength	Stronit Sachet
	Composition	Each Sachet Contains: Strontium ranelate…2g
	Diary No. Date of R& I & fee	Dy No. 16003: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other drugs affecting bone structure and mineralization
	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	Onita Sachet by Pharmevo
	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 approval letter from Licensing Division

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Evidence of required manufacturing facility / section approval letter from Licensing Division.**

261.	**Name and address of manufacturer / Applicant**	**M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Medipine 250mg Injection
	Composition	Each Vial Contains: Cefepime Hcl With L Arginine…250mg
	Diary No. Date of R& I & fee	Dy No. 16305: 07-03-2019 PKR 20,000/-: 06-03-2019
	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.	Could not be confirmed
	Me-too status	Cefstar Injection by M/s Barrett Hodgson
	GMP status	Last inspection report on the basis of inspection conducted 07-09-2021 states that their current GMP compliance level is rated as 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.

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.

262.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Wenlast 500mcg Tablet
	Composition	Each Film Coated Tablet Contains: Roflumilast…500mcg
	Diary No. Date of R& I & fee	Dy No. 14122: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiviral

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.	USFDA Approved
Me-too status	Raxus Tablets by Searle
GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

263. Name and address of manufacturer / Applicant	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
Brand Name +Dosage Form + Strength	Tenomide 25mg Tablet
Composition	Each Film Coated Tablet Contains: Tenofovir Alafenamid As Fumarate…25mg
Diary No. Date of R& I & fee	Dy No. 16140: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Antiviral
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.	USFDA Approved
Me-too status	Wymly Tablet by Genix
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

264. Name and address of manufacturer / Applicant	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
Brand Name +Dosage Form + Strength	Ticason 90mg Tablet
Composition	Each Film Coated Tablet Contains: Ticagrelor…90mg
Diary No. Date of R& I & fee	Dy No. 16141: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Platelet aggregation inhibitors
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.	USFDA Approved
Me-too status	Hitica Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

- Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

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	Vartan-S 49mg / 51mg Tablet
Composition	Each Film-Coated Tablet Contains: Sacubitril … 48.6 Valsartan (As Sacubitril Valsartan Sodium Salt Complex)… 51.4mg
Diary No. Date of R& I & fee	Dy No. 13532: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Angiotensin II receptor blockers, other combinations
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.	USFDA Approved
Me-too status	Sacuvia Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

266. Name and address of manufacturer / Applicant	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
Brand Name +Dosage Form + Strength	Glocina 60mg tablet
Composition	Each Film Coated Tablet Contains: Cinacalcet HCl…60mg
Diary No. Date of R& I & fee	Dy No. 16406: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Other anti-parathyroid agents
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.	USFDA Approved
Me-too status	Mimcipar Tablet by Genome
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

267. Name and address of manufacturer / Applicant	**M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad**
Brand Name +Dosage Form + Strength	Glizin D 5mg Tablet
Composition	Each Film Coated Tablet Contains: Dapagliflozin …5mg
Diary No. Date of R& I & fee	Dy No. 16027: 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 specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Daploz Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

268. Name and address of manufacturer / Applicant	**M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad**
Brand Name +Dosage Form + Strength	Glizin D 10mg Tablet
Composition	Each Film Coated Tablet Contains: Dapagliflozin …10mg
Diary No. Date of R& I & fee	Dy No. 16026: 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 specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Daploz Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

269. Name and address of manufacturer / Applicant	**M/s Fassgen Pharmaceuticals Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar**
Brand Name +Dosage Form + Strength	Perin 3mg XR Tablet
Composition	Each Extended Release Tablet Contains: Paliperidone…3mg
Diary No. Date of R& I & fee	Dy No. 15909: 07-03-2019

	PKR 20,000/-: 07-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
Me-too status	Lipard ER Tablet by Shrooq Pharma
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**

270. Name and address of manufacturer / Applicant	**M/s Fassgen Pharmaceuticals Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar**
Brand Name +Dosage Form + Strength	Perin 6mg XR Tablet
Composition	Each Extended Release Tablet Contains: Paliperidone…6mg
Diary No. Date of R& I & fee	Dy No. 15906: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
Me-too status	Lipard ER Tablet by Shrooq Pharma
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**

271. Name and address of manufacturer / Applicant	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
Brand Name +Dosage Form + Strength	Daclit Tablet 30mg
Composition	Each Film Coated Tablet Contains: Daclatasvir 2HCl…30mg
Diary No. Date of R& I & fee	Dy No. 14336: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antiviral
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.	USFDA Approved
Me-too status	Daclaget Tablet by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the innovator's product along with submission of full fee of registration.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

272. Name and address of manufacturer / Applicant	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
Brand Name +Dosage Form + Strength	Daclit Tablet 60mg
Composition	Each Film Coated Tablet Contains: Daclatasvir 2HCl…60mg
Diary No. Date of R& I & fee	Dy No. 14351: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antiviral
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.	USFDA Approved
Me-too status	Daclaget Tablet by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the innovator's product along with submission of full fee of registration.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

273. Name and address of manufacturer / Applicant	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
Brand Name +Dosage Form + Strength	Mibega Tablets 25mg
Composition	Each Film Coated Prolonged Release Tablet Contains: Mirabegron…25mg
Diary No. Date of R& I & fee	Dy No. 14344: 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 specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Mibega Tablet by Getz

GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

274. Name and address of manufacturer / Applicant	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
Brand Name +Dosage Form + Strength	Mibega Tablets 50mg
Composition	Each Film Coated Prolonged Release Tablet Contains: Mirabegron…50mg
Diary No. Date of R& I & fee	Dy No. 14345: 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 specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Mibega Tablet by Getz
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

275. Name and address of manufacturer / Applicant	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**
Brand Name +Dosage Form + Strength	Sofos 400mg Tablet
Composition	Each Film Coated Tablet Contains: Sofosbuvir…400mg
Diary No. Date of R& I & fee	Dy No. 14302: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antivirals
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.	USFDA Approved
Me-too status	Sovax Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

276. Name and address of manufacturer / Applicant	**M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan**

Brand Name +Dosage Form + Strength	Velpaget Tablets 400/100mg
Composition	Each Film Coated Tablet Contains: Sofosbuvir…400mg Velpatasvir…100mg
Diary No. Date of R& I & fee	Dy No. 14349: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antivirals for treatment of HCV infections
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.	USFDA Approved
Me-too status	Fosbu V Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

277. Name and address of manufacturer / Applicant	**M/s Libra Pvt Ltd 77-Peshawar Industrial Estate, Hayatabad Peshawar**
Brand Name +Dosage Form + Strength	Sepdase DS 5mg Tablet
Composition	Each Enteric Coated Tablet Contains: Serratiopeptidase …5mg
Diary No. Date of R& I & fee	Dy No. 16897: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Anti-inflammatory
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	Korzin Tablet by Opal Laboratories
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:

- **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.**

278. Name and address of manufacturer / Applicant	**M/s Libra Pvt Ltd 77-Peshawar Industrial Estate, Hayatabad Peshawar**
Brand Name +Dosage Form + Strength	Sepdase 10mg Tablet
Composition	Each Enteric Coated Tablet Contains: Serratiopeptidase …10mg
Diary No. Date of R& I & fee	Dy No. 16896: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Anti-inflammatory
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	Danzen DS Tablet by Helix
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:

- **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.**

279. Name and address of manufacturer / Applicant	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Peli PR Tablet 3mg
Composition	Each Prolonged Release Tablet Contains: Paliperidone…3mg
Diary No. Date of R& I & fee	Dy No. 14028: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
Me-too status	Lipard ER Tablet by Shrooq Pharma
GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**

280. Name and address of manufacturer / Applicant	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Peli PR Tablet 6mg
Composition	Each Prolonged Release Tablet Contains: Paliperidone…6mg
Diary No. Date of R& I & fee	Dy No. 14029: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
Me-too status	Lipard ER Tablet by Shrooq Pharma
GMP status	GMP certificate issued on 17-08-2021, based on

	evaluation conducted on 17-08-2021.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**

281. Name and address of manufacturer / Applicant	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
Brand Name +Dosage Form + Strength	Peli PR tablet 9mg
Composition	Each Tablet Contains: Paliperidone…9mg
Diary No. Date of R& I & fee	Dy No. 14030: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
Me-too status	Could not be confirmed
GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product. • 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 and stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**
- **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 and stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.**

282. Name and address of manufacturer / Applicant	**M/s Ipram International. Plot No. 26, S.S, National Industrial Zone, Rawat, Islamabad.**
Brand Name +Dosage Form + Strength	Iprol B 250mg Capsule
Composition	Each Capsule Contains: Saccharomyces boulardii …250mg

Diary No. Date of R& I & fee	Dy No. 16010: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antidiarrheal microorganisms
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	Enflor Capsule by Martin Dow
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. • 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 not a pharmaceutical drug product as per DRAP Act 2012.

283. Name and address of manufacturer / Applicant	**M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad**
Brand Name +Dosage Form + Strength	Base 250mg Sachet
Composition	Each Sachet Contains: Saccharomyces boulardii …250mg
Diary No. Date of R& I & fee	Dy No. 16010: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antidiarrheal microorganisms
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	Biflor sachet by Hilton
GMP status	Panel inspection conducted on 11-01-2019 recommended the renewal of DML.
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. • 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 not a pharmaceutical drug product as per DRAP Act 2012.

284. Name and address of manufacturer / Applicant	**M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore.**
Brand Name +Dosage Form + Strength	Wellbac Sachet
Composition	Each Sachet Contains Saccharomyces boulardii …250mg
Diary No. Date of R& I & fee	Dy No. 16459: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antidiarrheal microorganisms
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	Biflor sachet by Hilton
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].	• 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. • 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 not a pharmaceutical drug product as per DRAP Act 2012.

285. Name and address of manufacturer / Applicant	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila**
Brand Name +Dosage Form + Strength	Azil C Tablet 40/12.5mg
Composition	Each Film Coated Tablet Contains: Azilsartan Medoxomil…40mg Chlorthalidone…12.5mg
Diary No. Date of R& I & fee	Dy No. 16578: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Antihypertensive
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.	USFDA Approved
Me-too status	N/A
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Application on Form 5D along with differential fee since the applied formulation is not yet registered in Pakistan. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per follow along with submission of full fee of registration: Each Film Coated Tablet Contains: Azilsartan (as medoxomil).…40mg Chlorthalidone…12.5mg

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**
- **Application on Form 5D along with differential fee since the applied formulation is not yet registered in Pakistan.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

286. Name and address of manufacturer / Applicant	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila**
Brand Name +Dosage Form + Strength	Empazin Plus SR 12.5/1000mg Tablet
Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg

	Metformin HCl (Sustained Release)…1000mg
Diary No. Date of R& I & fee	Dy No. 14965: 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 specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	USFDA Approved
Me-too status	Diajard-M XR Tablet by Highnoon
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**

287. Name and address of manufacturer / Applicant	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila**
Brand Name +Dosage Form + Strength	Osemezone Tablet 500/20mg
Composition	Each Delayed Release Tablet Contains: Naproxen Sodium Enteric Coated…500mg Esomeprazole As Magnesium Trihydrate Film Coated…20mg
Diary No. Date of R& I & fee	Dy No. 16582: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Propionic acid derivatives
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.	USFDA Approved
Me-too status	Proxen-ES DR Tablet by Martin Dow
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the innovator's product along with submission of full fee of registration.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**

288. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore**
Brand Name +Dosage Form + Strength	Peridim P 6mg SR Tablet
Composition	Each Tablet Contains: Paliperidone…6mg
Diary No. Date of R& I & fee	Dy No. 16080: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
Me-too status	Lipard ER Tablet by Shrooq Pharma
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**

289. Name and address of manufacturer / Applicant	**M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore**
Brand Name +Dosage Form + Strength	Peridim X 9mg SR Tablet
Composition	Each Tablet Contains: Paliperidone…9mg
Diary No. Date of R& I & fee	Dy No. 16099: 07-03-2019 PKR 20,000/-: 06-03-2019
Pharmacological Group	Other antipsychotics
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.	USFDA Approved
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. • Revise your label claim as per the innovator's product along with submission of full fee of registration. • Provide evidence of required manufacturing technology (OROS Push-Pull Technology) as per reference product. • 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 and stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.

Decision: Deferred for following:

- **Latest GMP inspection report conducted within a period of last three years.**
- **Revision of the label claim as per the innovator's product along with submission of full fee of registration.**
- **Evidence of required manufacturing technology i.e. OROS Push-Pull Technology which is required for manufacturing of applied product as evident from the review report of the innovator's product.**
- **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 and stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.**

a) Deferred cases

290.	**Name and address of manufacturer / Applicant**	**M/s Intervac (Pvt) Ltd., 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan**
	Brand Name +Dosage Form + Strength	Oxytofas- DS Injection
	Composition	Each 100ml contains: Oxytocin (Synthetic)…….2000IU
	Diary No. Date of R& I & fee	Dy.No.8144; 10-07-2017; Rs.20,000/- (10-07-2017)
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Oxytovet Injection Of M/S International Pharma Labs.
	GMP status	Last inspection conducted on 28-02-2017 & 17-03-2017 and report concludes that panel recommend the renewal of injectable section (veterinary) and vaccines section (veterinary).
	Remarks of the Evaluator	
	Decision of 288th meeting of Registration Board: Deferred for the clarification of manufacturing outline as its not inline with the product approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
	Response by the firm: Firm has submitted me-too status along with print out from DRAP website database of registered drugs as follows Name: Oxytovet Injection Manufacturer: International Pharma Registration Number: 074756	
	Decision of 321st meeting of Registration Board: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
	Response by the firm: Firm has submitted copy of letter of grant of amendments / additional section approval dated 11-04-2017 specifying Veterinary Liquid Vials Injection (Hormone) section.	
	Decision: Registration Board decide do defer the instant application while referring to its 313th meeting wherein Board endorsed the following recommendations of Expert Working group on Veterinary Drugs: **"The Expert Working Group on Veterinary Drugs deliberate the case and decided to allow for granting multidose vials for Oxytocin as per following details:** • **Oxytocin .... 10 UI upto 500ml as per Spanish authority approval or any pack size available in any other RRA.** • **Oxytocin .... 20 UI upto 50ml as per Australian Pesticides and Veterinary Medicine Authority approval or any pack size available in any other RRA."**	

291.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Orphesic Forte 650/50mg
	Composition	Each Tablet Contains: Paracetamol…….650mg Orphenadrine Citrate…….50mg
	Diary No. Date of R& I & fee	Dy. No 14697 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Narcotic analgesic combination
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Orthoflex-D 50mg Tablet of M/s Noa Hemis Karachi (Reg.# 075984)

	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]:	
	Decision of 321st and 323rd meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Response by the firm: Firm has revised the formulation as per the innovator's product along with submission of 30,000 fee vide slip number 6187383799 dated 20-07-2022. The revised formulation is approved by TGA Australia and its me-too status is also available in Pakistan. The revised formulation is as under: Each Tablet Contains: Paracetamol…….450mg Orphenadrine Citrate…….35mg	
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Paracetamol…….450mg** **Orphenadrine Citrate…….35mg**	

292.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Metasone GM/Metacort Plus Cream
	Composition	Each gram cream contains: Betamethasone (as valerate)……1.2mg Gentamycin (as sulfate)…….1mg Miconazole (as nitrate)……20mg
	Diary No. Date of R& I & fee	Dy No. 1686: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics and antifungal
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20g; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor anitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator	□ The firm was asked to submit complete finished product specifications and testing methods. However, the firm submitted specifications without complete testing method. □ The brand name shall be changed
	Previous decision (M287)	Decision: Deferred for the following: □ Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Submission by the firm: • Copy of last GMP inspection report dated 14/12/2020, Satisfactory level of GMP compliance.	

	The firm has revised the formulation from Betamethasone as Valerate 1.2mg/g to Betamethosone as valerate 1mg/g and submitted rs. 7,500/- vide challan number 26027666328 dated 11/02/2022. Each gram cream contains: Betamethasone (as valerate)……1.2mg Gentamycin (as sulfate)…….1mg Miconazole (as nitrate)……20mg • Generic status: Mycona-GB cream by M/s Valor Pharmaceuticals, Reg. No. 066358 • RRA Status: could not be confirmed **Decision of 321st meeting of Registration Board:** Deferred for: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Response by the firm: Firm vide its letter dated 03-11-2022 has requested to revise their formulation as under: Each Gram of Cream Contains: Betamethasone as Dipropionate…0.5mg (0.05%w/w) Gentamicin as sulphate…1mg (0.1%w/w) **RRA Status:** Diprogenta cream by MSD, (Germany Approved) **Me-too status:** Effigenta Cream by Mass Pharma However, the firm has not submitted any fee.
	Registration Board was apprised that the firm has submitted another request that the revised formulation requested by them vide their letter dated 03-11-2022 is already registered with them. **Decision: Deferred for:** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**

Agenda of Evaluator PEC-IV

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

a. Deferred cases

I. Form 5-F Cases

293.	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. 23834 dated: 31-08-2021
	Details of fee submitted	PKR 20,000/- dated: 08/03/2021 PKR 10,000/- dated: 11/05/2020
	The proposed proprietary name / brand name	**Montisim 5mg tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable tablet contains: Montelukast as sodium…….5mg
	Pharmaceutical form of applied drug	Red colored, Round shaped, chewable tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Montelukast 5mg chewable tablet, Accord Healthcare Limited, United Kingdom, MHRA Approved.
	For generic drugs (me-too status)	Montiget 5mg chewable tablet, Getz Pharma (Pvt) Ltd. Reg# 034837
	GMP status of the Finished product manufacturer	Copy of cGMP issued on 23-07-202 on the basis of evaluation conducted on 09-07-2020
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City.
	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 montelukast sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Sulfoxide impurity, Cis Isomer, methylketone, methylstyrene 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 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (201310301, 201310302, 201310303)
	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 Singulair 5mg tablet Batch No# S018860 by Merck Sharp & Dohme limited UK by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Singulair 5mg tablet by Merck Sharp & Dohme limited UK in Acid media (pH 1.0-1.2) & Acetate buffer 4.5pH

		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 and specificity.

STABILITY STUDY DATA

Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials, Base Linhai Zone, Taizhou City.		
API Lot No.	11001-181210		
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: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20TRn006	20TRn009	20TRn010
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	10-2020	11-2020	11-2020
Date of Initiation	23-11-2020	23-11-2020	23-11-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No . ZJ20180033 issued by China food and Drug Control administration valid until 14.03.2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 3, form 7 and commercial invoice (Invoice# TY119146 Dated: 28-02-2019 with received quantity i.e. 15 kg) of Montelukast Batch No# 11001-181210 with attestation of DRAP Lahore dated: 11-03-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.1	Differential fee according to as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2012	Differential fee of Rs:10000/- deposit slip # 34803402245 dated: 11-05-2022 submitted

2.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Latest cGMP certificate submitted
3.	1.5.15 – 1.5.20	Submit Original Commitment	Signed original commitments submitted.
4.	2.3.R.1.1	Assay of Drug substance mentioned is 94.24% while in Certificate of Analysis of Drug substance Assay is 99.39%. Clarification is required.	Assay result 94.24% is result of montelukast on as is basis (the content of montelukast in montelukast sodium API), while the result 99.39% in Certificate of analysis of Drug substance under assay is result on dried basis.
5.	3.2.S.4.2	USP specify montelukast dicyclohexylamine as reference standard in drug substance assay testing while you have used montelukast sodium as reference standard. Clarification is required.	We used montelukast sodium as working standard which was standardized against Montelukast dicyclohexylamine CRS Lot#Y0001436 B#2. CoA of montelukast dicyclohexylamine Reference standard is given under section 3.2.P.6 Reference standard or materials and also attached (As the primary reference standards are costly and have small quantities, reference standards used in routine test of batch/product analysis are made in-house against primary reference standard. The in-house reference standards are working/secondary reference standards).
6.	3.2.P.5.2	• USP specify montelukast dicyclohexylamine as reference standard in drug product analytical testing method while you have used montelukast sodium as working standard. Clarification is required.	We used montelukast sodium as working standard which was standardized against Montelukast dicyclohexylamine CRS Lot#Y0001436 B#2. CoA of montelukast dicyclohexylamine Reference standard is given under section 3.2.P.6 Reference standard or materials and also attached (As the primary reference standards are costly and have small quantities, reference standards used in routine test of batch/product analysis are made in-house against primary reference standard. The in-house reference standards are working/secondary reference standards).
7.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any). • 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) • Documents for the procurement of API with approval from DRAP (in case of import).	• NA • Real time stability data summary sheets are attached. • Compliance record of HPLC Software 21CFR and audit trail reports on product testing are attached. • Record of digital data logger for temperature and humidity monitoring of stability chambers is attached. • Import documents submitted.

Previous Decision (M-320) : Registration Board deferred the case for Scientific justification for use of montelukast sodium as working standard instead of montelukast dicyclohexylamine specified by USP monograph.

Reply: We performed analysis of montelukast sodium drug substance against **Montelukast dicyclohexylamine CRS Lot#Y0001436 B#2** as recommended in USP monograph of montelukast

sodium. CoA of montelukast dicyclohexylamine CRS and pictures of Reference standard vial and label are attached. Analytical report of drug substance containing HPLC spectra of montelukast dicyclohexylamine CRS and FTIR identification Scan of drug substance against montelukast dicyclohexylamine CRS is attached As per USP monograph for montelukast sodium tablet, percentage of labeled amount of montelukast is to be calculated in tablet for which we used montelukast sodium working standard with known percentage of montelukast (94.24%) calculated against montelukast dicyclohexylamine CRS. Certificate of working standard attached.		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Manufacturer will perform analysis of finished product with montelukast dicyclohexylamine as reference standard as specified by USP monograph for the commercial batches.**		
294.	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.23836 dated: 31-08-2021
	Details of fee submitted	PKR 20,000/- dated: 22-02-2021 PKR 10,000/- dated: 11/05/2020
	The proposed proprietary name / brand name	**Montisim 10mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Montelukast as sodium…….10mg
	Pharmaceutical form of applied drug	Yellow colored, Round shaped, film coated tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Montelukast 10mg tablet, Accord Healthcare Limited, United Kingdom, MHRA Approved.
	For generic drugs (me-too status)	Montiget 10mg tablet, Getz Pharma (Pvt) Ltd. Reg# 034838
	GMP status of the Finished product manufacturer	Copy of cGMP issued on 23-07-202 on the basis of evaluation conducted on 09-07-2020
	Name and address of API manufacturer.	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials Base Linhai Zone, Taizhou City.
	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 montelukast sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Sulfoxide impurity, Cis Isomer, methylketone, methylstyrene 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (201310301, 201310302, 201310303)
	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 Singulair 10mg tablet Batch No# S032494 by Merk Sharp & Dohme limited UK by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Singulair 10mg tablet by Merk Sharp & Dohme limited UK in Acid media (pH 1.0-1.2) & Acetate buffer 4.5pH 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 and specificity.

STABILITY STUDY DATA

Manufacturer of API	ZHEJIANG TIANYU PHARMCEUTICALS CO., LTD. No. 15, Donghai 5th Avenue, Zhejiang Provincial chemical and medical Raw Materials, Base Linhai Zone, Taizhou City.		
API Lot No.	11001-181210		
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: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20TRn003	20TRn007	20TRn008
Batch Size	2000 tab	2000 tab	2000 tab

Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	11-11-2020	11-11-2020	11-11-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No . ZJ20180033 issued by China food and Drug Control administration valid until 14.03.2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of form 3, form 7 and commercial invoice (Invoice# TY119146 Dated: 28-02-2019 with received quantity i.e. 15 kg) of Montelukast Batch No# 11001-181210 with attestation of DRAP Lahore dated: 11-03-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.1	Differential fee according to as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2012	Differential fee of Rs:10000/- deposit slip # 34803402245 dated: 11-05-2022 submitted
2.	1.3.5.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Latest cGMP certificate submitted
3.	1.5.15 – 1.5.20	Submit Original Commitment	Signed original commitments submitted.
4.	2.3.R.1.1	Assay of Drug substance mentioned is 94.24% while in Certificate of Analysis of Drug substance Assay is 99.39%. Clarification is required.	Assay result 94.24% is result of montelukast on as is basis (the content of montelukast in montelukast sodium API), while the result 99.39% in Certificate of analysis of Drug substance under assay is result on dried basis.
5.	3.2.S.4.2	USP specify montelukast dicyclohexylamine as reference standard in drug substance assay testing while you have used montelukast sodium as reference standard. Clarification is required.	We used montelukast sodium as working standard which was standardized against Montelukast dicyclohexylamine CRS Lot#Y0001436 B#2. CoA of montelukast dicyclohexylamine Reference standard is given under section 3.2.P.6 Reference standard or materials and also attached (As the primary reference standards are costly and have small quantities, reference standards used in routine test of batch/product analysis are made in-house against primary reference standard. The in-

			house reference standards are working/secondary reference standards).
6.	3.2.P.5.2	• USP specify montelukast dicyclohexylamine as reference standard in drug product analytical testing method while you have used montelukast sodium as working standard. Clarification is required.	We used montelukast sodium as working standard which was standardized against Montelukast dicyclohexylamine CRS Lot#Y0001436 B#2. CoA of montelukast dicyclohexylamine Reference standard is given under section 3.2.P.6 Reference standard or materials and also attached (As the primary reference standards are costly and have small quantities, reference standards used in routine test of batch/product analysis are made in-house against primary reference standard. The in-house reference standards are working/secondary reference standards).
7.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any). • Submit real time • stability summary sheets for 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) • Documents for the procurement of API with approval from DRAP (in case of import).	• NA • Real time stability data summary sheets are attached. • Compliance record of HPLC Software 21CFR and audit trail reports on product testing are attached. • Record of digital data logger for temperature and humidity monitoring of stability chambers is attached. • Import documents submitted.

Previous Decision (M-320): Registration Board deferred the case for Scientific justification for use of montelukast sodium as working standard instead of montelukast dicyclohexylamine specified by USP monograph.

Reply: We performed analysis of montelukast sodium drug substance against **Montelukast dicyclohexylamine CRS Lot#Y0001436 B#2** as recommended in USP monograph of montelukast sodium. CoA of montelukast dicyclohexylamine CRS and pictures of Reference standard vial and label are attached. Analytical report of drug substance containing HPLC spectra of montelukast dicyclohexylamine CRS and FTIR identification Scan of drug substance against montelukast dicyclohexylamine CRS is attached
As per USP monograph for montelukast sodium tablet, percentage of labeled amount of montelukast is to be calculated in tablet for which we used montelukast sodium working standard with known percentage of montelukast (94.24%) calculated against montelukast dicyclohexylamine CRS. Certificate of working standard attached.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will perform analysis of finished product with montelukast dicyclohexylamine As reference standard as specified by USP monograph for the commercial batches.**

II. Form 5 Cases:

295.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	**Tramax 100mg SR Capsule**

	Composition	Each Sustained Release Capsule Contains: Tramadol Hcl…100mg
	Diary No. Date of R& I & fee	Dy.No. 41495 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Narcotic analgesic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	CONZIP 100mg Capsules of (USFDA approved)
	Me-too status	Zultra SR 100mg of M/s. Wilshire Laboratories
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator	Submit Master formula, manufacturing method, analytical method CIP-TRAMADOL ER (tramadol hydrochloride) extended-release) capsules are a new formulation of tramadol HCl for analgesia. The drug product consists of extended release film coated white beads and an immediate release tablet encapsulated in white opaque, size 1, 0 and 00, hard gelatin capsules

Dosage	Immediate release	Extended release
100 mg	25 mg	75 mg

Previous Decision (M-322): Deferred for review of formulation against the innovator product.

Reply by firm: We want to inform you that we had applied for Tramadol HCl 100mg as "Tablet". There was typographical error in the last reply sent in response to letter number F.1-1/2019/PEC-DRAP (AD PEC-IV) dated: 7th September, 2022. R & I copy of product is attached for reference.

We are also applying for the change in the label claim of the product

Name of Drug with Applied label claim	**Name of Drug with Proposed label claim**	**Fee for change in label claim**
Tramax 100mg SR Tablet Each Sustained Release Tablet Contains: Tramadol Hcl…100mg	Tramax 100mg SR Tablet Each Extended release Film Coated Tablet Contains: Tramadol Hcl…100mg	Deposit slip No# 50754384014 Rs:7500/- Dated: 23-01-2023

Approval status of product in Reference Regulatory Authorities	ULTRAM ER of USFDA

Remarks: Film coating is not mentioned in ULTRAM ER
Master formula and manufacturing method is not submitted.

Decision: Registration Board deferred the case for submission of Master formula and manufacturing method of the applied formulation.

296.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Orofit Capsule 120mg
	Composition	Each capsule contains: Orlistat…..120mg
	Diary No. Date of R& I & fee	Dy. No. 39, 03-11-2016 , Rs.20,000/- (31-10-2016)
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per leader price
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Registration Number: 068689 Brand Name: Orly Capsules 120 mg

		Manufacturer Name: Rotex Medica
	GMP status	Last GMP inspection of M/s High-Q Pharmaceuticals was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Remarks of the Evaluator	In reference regulatory authority the orlistat is approved in the form of pellets while the firm has applied for orlistat in the form of powder.
	Previous Decision (M-283): Deferred for the submission of Form 5 of applied formulation in line with the innovator product.	
	Reply by firm: Firm submitted form 5 with following label claim: Each Capsule Contains: Orlistat (as 50% w/w pellets) ……. 120mg (High Q specifications) **Source of pellets:** M/s Alphamed formulations, Pvt. Ltd, Sy. No.225, Sampanbole Village, Medchal-Malkajgiri District, Telangana, India. Firm submitted: • Certificate of analysis of pellets • GMP certificate #.Dis.No: 93420/TS/2022 of pellets manufacturer valid till 15-08-2023 • Long term stability data at Zone IVa till 24 months, wherein test for related substances have been performed. ***Fee for imported pellets not submitted***	
	Decision: Approved with USP specifications as per following label claim: **Each Capsule Contains:** **Orlistat (as 50% w/w pellets) ……. 120mg** **Registration letter will be issued after submission of fee for imported pellets as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

M/s AGM Pharmaceuticals **. (New DML)**
CLB in its 283rd meeting held on 28th October 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five (03) sections to M/s AGM Pharmaceuticals

1.	Tablet (General)
2.	Capsule (General)
3.	Dry Powder Injectable (Cephalosporin)

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

Capsule (General)
02 Molecules/ 02 Products

297.	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, 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. 195 dated 03-01-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 94816553563
	The proposed proprietary name / brand name	**Pirogm 20mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard gelatin capsule contains: Piroxicam…….20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP
	Proposed Pack size	2×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Feldene 20 mg Capsule by M/s Pfizer of USFDA Approved
	For generic drugs (me-too status)	Feldene 20 mg Capsule by M/s Pfizer Reg#006349
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	Alcon Biosciences Pvt Ltd. A-1/2104, Phase-III, GIDC, VAPI, 396195, 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 Piroxicam is present in BP. 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 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ALC/PCM/131205, ALC/PCM/131206, ALC/PCM/131207)
	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 Feldene capsule 20mg by Pfizer by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Feldene capsule 20mg by Pfizer 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 accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Alcon Biosciences Pvt Ltd. A-1/2104, Phase-III, GIDC, VAPI, 396195, District Valsad, Gujrat India.		
API Lot No.	PCM-22041		
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.	TRC001	TRC002	TRC003
Batch Size	1500	2000	2000
Manufacturing Date	27-11-21	29-11-21	30-11-21
Date of Initiation	30-11-21	30-11-21	30-11-21
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 of Form invoice (invoice# AV/I/00062/22-23) dated: 13-11-2021 specifying import 200gm Piroxicam (Batch# PCM-22041)
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: During Evaluation it was observed that AGM pharmaceuticals, Gujranwala and Pharman Pharmaceutical, Gujranwala DML have same Name of Production in charge.

S.No	Section	Shortcomings Communicated	Reply
1.	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.	Not submitted.
2.	3.2.S.4.3	Analytical Method Verification studies Submitted by HPLC while B.P specifications are claimed by drug product manufacturer.	USP specifications was applied for API testing that's why HPLC AMV studies were submitted. **Evaluation: Firm claimed BP specification in COA of drug substance and limits are also according to BP i.e Assay limits applied are 98.5% to 101.0% which are according to BP specifications while USP specifications for Assay are 97.0% to 103.0%**

3.	3.2.P.1	DC granular used as excipient in formulation. Explain what is DC granular.	DC lactose granular was used but lactose word was skipped. It is a typographical error. Revised documents submitted.
4.	3.2.P.5.1	Submit complete Specifications as per USP monograph.	Specification as per USP monograph are attached
5.	3.2.P.5.2	Submit analytical testing method of drug product instead of USP monograph presentation.	Analytical testing method of drug product submitted.
6.	3.2.P.5.4	Water content as per USP monograph not Performed. Clarification is required.	Water content is tested on next time point and report is attached.
7.	3.2.P.8	Documents for the procurement of API with approval from DRAP.	Commercial invoice without DRAP approval submitted.

Decision: Deferred for following:

- **Submission of 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.**
- **Justification for applying USP monograph for the drug substance analysis and analytical method verification studies whereas drug product manufacturer has claimed BP specifications for the drug substance.**
- **Documents for the procurement of API with approval from DRAP.**

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

298.	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, 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. 373 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 12237124
	The proposed proprietary name / brand name	**AG-gab 75mg capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Pregablin…75mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	Inhouse
	Proposed Pack size	2×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Alzain 75 mg Capsules, Hard Dr. Reddy's Laboratories (UK) Ltd (MHRA Approved)
	For generic drugs (me-too status)	Gabica Capsule 75 mg by M/s Getz Pharma Pvt

		Ltd (Reg # 047365)
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	CTX Lifesciences Pvt. Ltd.,Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Pregablin is present in BP. 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 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PG120001, PG120002, PG120003)
	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 Gabica 75mg capsules BY Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Pregablin 75mg capsule by Getz Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	CTX Lifesciences Pvt. Ltd.,Block No: 251-252, Sachin- Magdalla Road GIDC Sachin, Surat – 394 230 GUJARAT, INDIA
API Lot No.	22PL000056
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.	TRC028	TRC029	TRC030
Batch Size	1500	1500	1500
Manufacturing Date	04-12-21	06-12-21	07-12-21
Date of Initiation	07-12-21	07-12-21	07-12-21
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 issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form invoice (invoice# EI/3022100460) dated: 16-11-2021 specifying import 310gm Pregabalin (Batch# 22PL000056)
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	Section	Shortcomings Communicated
1.	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
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
5.	3.2.P.2.1.1	Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
6.	3.2.P.2.2.1	Revise Pharmaceutical equivalence shall be provided in accordance with BP monograph
7.	3.2.P.5.1	• Product is available in BP pharmacopeia while applied formulations are In-house. Clarify • Dissolution is not included in specification Clarify
8.	3.2.P.5.2	Submit Analytical testing method of Pregabalin capsule instead of presentation of Pregabalin Drug substance monograph of USP Pharmacopeia.
9.	3.2.P.5.3	Revise Analytical method verification shall be provided in accordance with BP monograph.
10.	3.2.P.5.4	Results in COA's of 03 batches are different from stability summary sheets. Clarify.
11.	3.2.P.8	• Documents for the procurement of API with approval from DRAP.

		• Results in COA's of Accelerated stability studies and Real time stability studies of 03 batches are different from stability summary sheets. Clarify. • Tests of stability batches need to be carried out for all time points as per BP monograph.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

Tablet (General)
03 Molecules/ 03 Products

299.	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, 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. 371 dated 04-01-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 3260128396
	The proposed proprietary name / brand name	**Pirogm 20mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Piroxicam…….20mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP
	Proposed Pack size	2×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	Feldene 20 mg Tablet by M/s Pfizer Reg#010940
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	Alcon Biosciences Pvt Ltd. A-1/2104, Phase-III, GIDC, VAPI, 396195, District Valsad, Gujrat India.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Feldene Tablet 20mg by Pfizer by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is piroxicam 20mg by Pfizer in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply	Evaluation
1.	1.5.6	Mention the reference specifications of the finished product (drug product)	No reply	Firm applied on USP pharmacopeia but Tablet is

				not available in any pharmacopeia
2.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board.	Brexin 20mg by Pierre FABRE MEDICAMENT of ANSM France approved	• Brexin tablet is uncoated while applied formulation is film coated. • Tablet contain Piroxicam-beta-cyclodextrin while applied formulation contain Piroxicam. • Moreover Pharmaceutical Equivalence and CDP is conducted against Feldene Tablet of Pfizer which is dispersible tablet.

Decision: Deferred for evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any of the reference regulatory authority adopted by Registration Board in its 275th meeting.

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

300.	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, 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. 374 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
	The proposed proprietary name / brand name	**Ag-CIP 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl…250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 50MG film coated tablet. Manufactured M/s Aurobindo Phrma-Milpharm Ltd. MHRA Approved.
	For generic drugs (me-too status)	NOVIDAT 250mg tab by M/s Sami Pharma #011836
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021

	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	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 Ciprofloxacin Hydrochloride 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 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CPH1402007, CPH1402008, CPH1402009)
	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 Novidat 250mg tablet BY SAMI Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ciprofloxacin 250mg tablet Tablet by SAMI Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
API Lot No.	CPH2112137
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.	TRT-019	TRT-020	TRT-021
Batch Size	1500	1500	1500
Manufacturing Date	12-21	13-12-21	14-12-2021
Date of Initiation	15-12-21	15-12-21	15-12-21
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 issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
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.	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	Section	Shortcomings Communicated
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
2.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
4.	3.2.S.4.4	In COA by drug product manufacturer result for water content shows comply instead of value. Justify
5.	3.2.S.2.2.1	In CDP time points are up to 5,10,15,20,25,30 minutes while in calculation of F1 and F2 up to 5,10,15,20,25, 45 minutes are mentioned. Clarify. .
6.	3.2.P.5.3	Submit Protocols of Analytical method verifications.
7.	3.2.P.	COA of reference standard Ciprofloxacin Ethylenediamine Analoge
8.	3.2.P.8	Purchase documents for Ciprofloxacin HCl. COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. In raw data sheets Batch NO TRC-019, TRC-020, TRC-021 while in all other documents Batch no # TRT-019, TRT-020, TRT-021. Clarify

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Registration Board was further apprised that during evaluation it was identified that "Production In charge" of two firms i.e., M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala & M/s Pharman Pharmaceuticals 6 Km, Bohmaan Bath Road, Kalasky, Gujranwala, was same, as evident form submitted documents. Hence Registration Board advised PE&R Division to refer the case to Licensing Division for clarification/necessary action.

301.	Name, address of Applicant / Marketing Authorization Holder	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, Pakistan

	Name, address of Manufacturing site.	M/s AGM Pharmaceuticals Eminabad Road, G.T. Road, Gujranwala, 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. 374 dated 04-01-20223
	Details of fee submitted	PKR 30,000/-: Deposit slip # 434526355
	The proposed proprietary name / brand name	**G-Mol 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol…500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	20×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	New DML issued on 10/11/2021
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (Film coated Tablet) in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of application.	Firm submitted now Composition as core tablet without film coating excipients and also change label claim in section in 1.5.2 as Each tablet contains: Paracetamol….500mg **Evaluation: Firm applied in all application as film coated and also manufacturing of stability batches is done as film coated and stability studies conducted on film coated tablet.**

Decision: Registration Board deferred the application for submission of Product development, Pharmaceutical Equivalence ,CDP, Batch manufacturing record and complete stability studies for revised formulation of "uncoated tablet".

New/Additional section(s)

M/s Jaskan Pharmaceuticals (Pvt) Ltd.50-Sundar Industrial Estate, Lahore, Pakistan.
The Central Licensing Board in its 279th meeting held on 18th February, 2021 has considered and approved the grant of Seven (07) Section

Sr. No	Section	Molecules considered in 326th meeting	Products considered in 326th meeting
1	Injectable (Ampoule) General Section	01	01

Injectable (Ampoule) General Section

302.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceuticals (Pvt) Ltd. 50-Sundar Industrial Estate, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceuticals (Pvt) Ltd. 50-Sundar Industrial Estate, 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. 34286 dated 28-11-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 4471687486
	The proposed proprietary name / brand name	**Ondus 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule Contains: Ondansetron HCl Dihydrate Eq. to Ondansetron…8mg
	Pharmaceutical form of applied drug	Injection (IV/IM)
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	4ml x 1's & 4ml x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Injection 2mg/ml of Novartis Pharmaceuticals UK Limited, of MHRA approved.
	For generic drugs (me-too status)	Zofran Injection 8mg/4ml of M/s Novartis (P
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted on 26-10-2020
	Name and address of API manufacturer.	M/s Anugraha Chemicals Address: No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District , 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 Ondansetron HCl 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 60 months

		Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (AOND-17002, AOND-17003, AOND-17004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Zofran Injection Batch #A44W by M/s Novartis Pharma (Pakistan) Ltd.,. Pakistan performing quality tests (Appearance, Identification, pH, Particulate matter, BET, , Assay,).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals Address: No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District , India.		
API Lot No.	01701012205016		
Description of Pack (Container closure system)	Clear glass USP Type-I glass.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LR-01	LR-02	LR-03
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	29-06-2022	29-06-2022	29-06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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 License No. DCD/MFG/Application Id-240 for M/s Anugraha Chemicals, issued by Drug Control Administration Karnataka India valid upto 13-02-2025 Copy of GMP certificate No# DCD/SPL-1/CR-1733/2021-22 , issued by Drug Control Administration Karnataka India issued on 31-01-2022 and valid for 01 year.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance certificate No # E-1572164621684 issued by DRAP office Lahore Dated;12-06-2022 Invoice No# ZHI-CI/5999/0522 dated 27-May-2022 specifying import of ONDANSETRON HYDROCHLORIDE(USP Specification) of Batch No # 01701012205016

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

Remarks of Evaluator:

S. No	Section	Shortcomings Communicated	Reply
1.	1.5.2	Strength of Active ingredient shall be stated clearly. e.g each ml contains in case of Injectable.	Each 1.0 ml contains : Ondansetron hydrochloride dihydrate equivalent to ondansetron.....2.0 mg Annexure has been Attached.
2.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer are submitted.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance is submitted.
4.	3.2.S.7.3	Submit Real time stability studies of drug substance till shelf life or claimed retest period.	Real time stability studies of drug substance submitted till 60 months
5.	3.2.P.2.2.1	In Pharmaceutical equivalence Zofran injection is used while manufacturer mentioned is Neutro pharma. Submit details of product against which Pharmaceutical equivalence conducted.	It was a typographical mistake corrected detail of product against which pharmaceutical equivalence has been conducted. Copy has been Submitted (Novartis Pharma Zofran Injection is used.)
6.	3.2.P.3.5	Brief description of process validation including the proposed protocol shall be described.	Process validation including the proposed protocol is submitted
7.	3.2.S.5.2	Detailed analytical procedures used for testing the drug product shall be provided	Detailed analytical procedures used for testing the drug product is submitted.
8.	3.2.P.8	• Initiation date of stability studies not mentioned in stability studies summary sheets. • In stability summary sheets batch size is 100 injection while in BMR's 1000 injections. Clarification is required • In stability summary sheets Date of manufacturing is 29-06-2024. Clarify. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing	• Stability studies summary sheets with Initiation of stability studies dates submitted. • Typographical mistake is corrected and documents attached.(1000 injection is batch size). • Typographical mistake is corrected and documents attached.(Date of manufacturing is 29-06-2022) • Compliance Record of HPLC software 21CFR & audit trail reports on product testing 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.**

M/s Caraway Pharmaceuticals Plot 12, Street N-3 RCCI Rawat Islamabad
The Central Licensing Board in its 287th meeting held on 24th June, 2022 has considered and approved the grant of One (01) additional

1. Liquid Syrup (General) Section

Sr. No	Section	Molecules considered in 326th meeting	Products considered in 326th meeting
1	Liquid Syrup (General) Section	01	01

303.	Name, address of Applicant / Marketing Authorization Holder	**M/s Caraway Pharmaceuticals, RCCI Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals, Plot 12, Street N-3 RCCI 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. 33133 dated 18-11-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 891451929
	The proposed proprietary name / brand name	ONDENLES Syrup 4mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml contains: Ondansetron Hydrochloride Dihydrate eq to Ondansetron ……..4mg.
	Pharmaceutical form of applied drug	Oral (Liquid Syrup)
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist. (Anti-emetic)
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZOFRAN (4mg/5ml) oral solution USFDA Approved
	For generic drugs (me-too status)	Onseron syrup by M/s Indus Pharma (Reg#058677)
	GMP status of the Finished product manufacturer	Last inspection conducted on 22-02-2022 and panel unanimously recommend for renewal of DML and grant of new section.
	Name and address of API manufacturer.	M/s Anugraha Chemicals Address: No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District , 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 Ondansetron HCl 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 09 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (AOND-10003, AOND-10004, AOND-10005)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Onseron 4mg/5ml syrup by M/s Indus Pharma (Pvt.) Ltd by performing quality tests (Description, Identification, pH, Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Anugraha Chemicals Address: No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District , India.		
API Lot No.	AOND-21015		
Description of Pack (Container closure system)	Amber color PET bottle packed in unit carton (1's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-052	T-053	T-054
Batch Size	250 Bottles	250 Bottles	250 Bottles
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)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of License No. DCD/MFG/Application Id-240 for M/s Anugraha Chemicals, issued by Drug Control Administration Karnataka India valid upto 13-02-2025

		Copy of GMP certificate No# DCD/SPL-1/CR-1733/2021-22 , issued by Drug Control Administration Karnataka India issued on 31-01-2022 and valid for 01 year.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Clearance certificate No # E-5712765637 issued by DRAP office Islamabad Dated; 21-Feb-2022 Invoice No# exp-039 dated 31-Dec-2021 specifying import of Ondansetron Hydrochloride (USP Specification) of Batch No # AOND-21015
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	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) instead of drug product shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) submitted.
2.	3.2.P.5.2	In assay of standard preparation an accurately weighed quantity of Ondansetron Hydrochloride mentioned . Elaborate what is accurate quantity.	9mg Ondanseron Hydrochloride Rs/Ws weighed and diluted 100ml with mobile phase, to get 90µg per ml concentration. Filter through filter paper having porosity 0.45 µm.

Decision: Approved.

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

Registration Board further directed the PE&R Division to issue registration letter of instant application after cancellation of registration of products which were granted for the "Liquid Injectable Vial (General) section of M/s Caraway Pharmaceuticals, RCCI Rawat, Islamabad since CLB in its 287th meeting has declared that frim's "Liquid Vial section (Infusion) was changed to Syrup section.

M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore

CLB in its 273rd meeting held on 15th January 2020, has approved the following 3 additional sections of M/s British Pharmaceuticals

1.Capsule Section (General)
2.Dry Powder Section (General)
3.Tablet Section (General)

Sr. No	Section	Molecules considered in 326th meeting	Products considered in 326th meeting
1	Tablet Section (General)	01	01

304.	Name, address of Applicant / Marketing Authorization Holder	M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceuticals. 23-Km Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20289 dated 18-07-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 86328899583
	The proposed proprietary name / brand name	Bricit 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains:- Cetirizine Dihydrochloride ……10mg
	Pharmaceutical form of applied drug	White oblong shape film coated tablet
	Pharmacotherapeutic Group of (API)	Histamine Receptor Antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's, 10x10's, Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cetirizine film coated tablets of MHRA Approved
	For generic drugs (me-too status)	Histex 10mg Tablet M/s Pharmatec Pakistan, Reg. No. 020342
	GMP status of the Finished product manufacturer	Renewal of DML granted dated 12-01-2022.
	Name and address of API manufacturer.	M/s Sreekara Organics Plot No. 159/A, S.V. Co-op. Ind. Estate India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Cetirizine Dihydrochloride 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 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: CZ/V/00611, CZ/V/00511, CZ/V/00411)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Rigix 10mg tablet by AGP Pharma. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Bricit 10mg tablet by British Pharma 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.

STABILITY STUDY DATA

Manufacturer of API	M/s Sreekara Organics Plot No. 159/A, S.V. Co-op. Ind. Estate India		
API Lot No.	CTZ03521		
Description of Pack (Container closure system)	Alu-Pvc blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	B1	B2	B3
Batch Size	24000 Tablets	24000 Tablets	24000 Tablets
Manufacturing Date	26-08-2021	26-08-2021	26-08-2021
Date of Initiation	27-08-2021	27-08-2021	27-08-2021
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 GMP certificate # L.Dis.No:82408/TS/2022 issued by Drug Control Administration Governament of Telangana issued on 15-03-2022 and valid until 14-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted 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	Section	Shortcomings Communicated	Reply

1.	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.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin submitted.
2.	2.3.R.1.1	In manufacturing of stability batches production Overage of Cetirizine 2HCl is Used. Clarification is required.	Overage was not used in stability batches. There was a calculation error observed in the manufacturing order. Revised document is attached.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the British Pharmaceuticals for drug substance(s) instead of drug product shall be submitted.	Analytical Method Verification studies including accuracy and repeatability performed by the British Pharmaceuticals for drug substance(s) are submitted. But specificity not submitted.
4.	3.2.S.4.4	In COA of drug substance by drug product manufacturer Residue on ignition and loss on drying are mentioned as complies and ok. Clarify.	Revised COA is attached with values of Residue on ignition and loss on drying.
5.	3.2.P.5.2	The manufacturer shall mention dissolution test No as per requirement of USP monograph.	Dissolution Test 1 was used for testing of the product.
6.	3.2.P.5.3	Performance of accuracy & precision parameter during analytical method verification studies has not been conducted as per recommendations of ICH Q2 (R1) guidelines. Specificity is not done for drug product	**No reply submitted.**

Decision: Deferred for submission of following:

- **Performance of Specificity parameter in the analytical method verification studies of drug substance by drug product manufacturer.**
- **Analytical method verification studies of drug product** .

M/s Sayyed Pharmaceutical (Pvt) Ltd,67/2,Phase 3,Industrial estate, Hattar,Haripur.

CLB in its 274th meeting held on 07th April 2020, has approved the following 01 additional sections of M/s Sayyed Pharmaceutical (Pvt) Ltd

1.Tablet Section (Psychotropic)

Sr. No	Section	Molecules considered in 326th meeting	Products considered in 326th meeting
1	Tablet Section (Psychotropic)	01	01

305.	Name, address of Applicant / Marketing Authorization Holder	M/s Sayyed Pharmaceutical (Pvt) Ltd,67/2,Phase 3,Industrial estate,hattar,Haripur.
	Name, address of Manufacturing site.	M/s Sayyed Pharmaceutical (Pvt) Ltd,67/2,Phase 3,Industrial estate,hattar,Haripur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24206 dated 26-08-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 1459901525
	The proposed proprietary name / brand name	**Phenosyd 30mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Phenobarbital…….30mg
	Pharmaceutical form of applied drug	White, Round shaped, bisect tablet
	Pharmacotherapeutic Group of (API)	Barbiturates
	Reference to Finished product specifications	USP
	Proposed Pack size	3×10's and 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(MHRA Approved).
	For generic drugs (me-too status)	Lenton 30 mg Tablet by M/s Valor Pharma Reg#063353
	GMP status of the Finished product manufacturer	New Section approved on 09/04/2020 Tablet (Psychotropic)
	Name and address of API manufacturer.	M/s Nantong Jinghua Pharmaceutical Co.,Ltd No.20,3 Haibin road,Yanhai Economic development zone, Rudong,Nantong,Jiangsu,China, 226407
	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 Phenobarbital 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 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(BBT72012001-RD,BBT72012002-RD BBT72012003-RD)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Comparator product that is Phenobarb 30mg tablet by M/S Star Laborotories (Pvt) Ltd by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Phenobarb 30mg tablet by M/S Star Laborotories (Pvt) Ltd in Acid media (pH 1.2) (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.

STABILITY STUDY DATA

Manufacturer of API	M/s Nantong Jinghua Pharmaceutical Co.,Ltd No.20,3 Haibin road,Yanhai Economic development zone, Rudong,Nantong,Jiangsu,China, 226407	
API Lot No.	BBT2021056	
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (3×10's)	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	Trial-01	Trial-02
Batch Size	5000 tab	5000 tab
Manufacturing Date	04-2022	04-2022
Date of Initiation	19-04-2022	19-04-2022
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 GMP certificate No# JS20180829 issued by China Food and Drug Administration issued on 01-06-2018 and valid until 31-05-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Import Authorization No# P.No.99/2021-CD dated 04-03-20216 & Form 6 and invoice (invoice# NTJH N4835) dated: 13-07-2021 cleared by DRAP Peshawar office dated 29-07-2021 specifying import 1Kg Phenobarbitone (Batch# BBT2021056)
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	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.4	Certificate of Analysis (CoA) of the same batch from Drug	Certificate of Analysis (CoA) of the same batch from Drug Substance /Active Pharmaceutical

		Substance /Active Pharmaceutical Ingredient manufacture for drug substance used during product development and stability studies	Ingredient manufacture for drug substance used during product development and stability studies is submitted.
2.	3.2.P.5.4	Batch analysis of Clonazepam submitted. Clarification is required.	Batch analysis of Clonazepam was mistakenly submitted. Batch analysis of Phenobarbital tablet is Attached.
3.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Submit Stability studies of 6 months.	• Form 6, Commercial Invoice and import Authorization from Controlled drugs submitted. • Stability studies of 6th months 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.**

M/s Citi Pharma Private Limited. 3 K.M, Head Balloki Road, phool Nagar Distt, Kasur CLB in its 282nd meeting held on 31st August 2021, has approved the following three (03) additional sections of M/s Citi Pharma Private Limited

1.Capsule (Cephalosporin) Section
2.Oral Dry Powder Suspension (Cephalosporin)
3.Dry Powder Injection (Cephalosporin)

Sr. No	Section	Molecules considered in 326th meeting	Products considered in 326th meeting
1	Dry Powder Injection (Cephalosporin)	01	03

306.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Address: 3 K.M, Head Balloki Road, phool Nagar Distt, Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34504 dated 29-11-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 78974267
	The proposed proprietary name / brand name	Citzadime Injection 250mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftazidime……. 250mg (with Sodium carbonate)
	Pharmaceutical form of applied drug	Parenteral
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP

	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime 250 mg powder for solution for injection by Sandoz Limited of MHRA approved
	For generic drugs (me-too status)	Cefcom 250mg of M/s Barrett Hodgson
	GMP status of the Finished product manufacturer	Last GMP inspection conducted on 07-06-2022 and report concludes that firm has currently fair compliance of GMP.
	Name and address of API manufacturer.	Harbin Pharmaceutical Group Co., Ltd General Pharm. Factory No. 109 Xuefu Road Nanang District Harbin People Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ceftazidime 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 36 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (A20021202, A20021203, A20021204)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Cefcom 250mg Injection IV/IM by M/s BARRETT HODGSON . Pakistan performing quality tests (Identification, Assay, Constituted Solution, pH, Sterility, BET).
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Harbin Pharmaceutical Group Co., Ltd General Pharm. Factory
API Lot No.	A202107010
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.	TCS-CD001	TCS-CD002	TCS-CD003
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation			
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form 6 for Ceftazidime specifying quantity 5Kg from Harbin Pharmaceutical Group Co., Ltd No. 109 Xuefu Road Nanang District Harbin People Republic of China submitted dated: 03-06-2021
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	
6.	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	Reply
1.	1.5.6	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin. ii. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	**Firm submitted Request for Hold/Withdrawal of Dossier:** **"**We the Citi (Pvt) Ltd. Lahore wish to hold and withdraw our Registeration dossier of Ceftazidime Injection (250mg, 500mg, and 1g) submitted due to some technical issues in dossier compilation."
2.	2.3.A.1	Provide evidence of atomic absorption spectrophotometer	
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.4.2	Detailed analytical procedures for the testing of drug substance by drug product manufacturer shall be provided.	
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	
6.	3.2.S.4.4	• Provide Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture used during product development and stability studies.	

		• Justification of not performing content of Sodium carbonate as recommended by USP monograph.	
7.	3.2.P.1	Applied formulation does not show eq of pentahydrate	
8.	3.2.P.3.3	In Manufacturing method solution form of injection is prepared . Clarify. Flow diagram for manufacturing of Ceftriaxon submitted.	
9.	3.2.P.2.6	Compatibility with diluent of Cefuroxime submitted. Clarify.	
10.	3.2.P.5.1	Your drug product specifications are not as per USP since many tests recommended by USP are not performed	
11.	3.2.P.5.2	Analytical testing method of different product submitted which are different from USP monograph. Justify why contents of sodium carbonate is not performed in the drug product also	
12.	3.2.P.5.3	Analytical method verification submitted by UV method while USP monograph specify by HPLC.	
13.	3.2.P.5.4	COA's of drug product show different specification than USP and different bacth No than mentioned in stability studies.	
14.	3.2.P.6	Provide COA and evidence of import of Ceftazidime, Delta-3-Isomer RS which is used in the analysis of drug product	
15.	3.2.P.8	• Data of stability batches will be supported by attested respective documents like chromatograms, • Initiation date of stability studies not mentioned • Drug product specifications are not as per USP Specification in stability studies. • Justify how initial testing results of Assay for Real time studies and Accelerated studies are different. • Justify how results in Accelerated stability studies same for 03 batches are same. • 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 acceded the firm's request of withdrawal and declared the instant application as disposed off. Registration Board further noted that firm's quota of priority consideration against the new sections will also be deducted keeping the fact of the consideration of instant application.

307.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Address: 3 K.M, Head Balloki Road, phool Nagar Distt, Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34505 dated 29-11-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 971862868
	The proposed proprietary name / brand name	**Citzadime Injection 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftazidime……. 500mg (with Sodium carbonate)
	Pharmaceutical form of applied drug	Parenteral
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime 500 mg powder for solution for injection by Sandoz Limited of MHRA approved
	For generic drugs (me-too status)	Cefcom 500mg of M/s Barrett Hodgson
	GMP status of the Finished product manufacturer	Last GMP inspection conducted on 07-06-2022 and report concludes that firm has currently fair compliance of GMP.
	Name and address of API manufacturer.	Harbin Pharmaceutical Group Co., Ltd General Pharm. Factory No. 109 Xuefu Road Nanang District Harbin People Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ceftazidime 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 36 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (A20021202, A20021203, A20021204)
	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	
	Analytical method validation/verification of product	

STABILITY STUDY DATA			
Manufacturer of API	Harbin Pharmaceutical Group Co., Ltd General Pharm. Factory		
API Lot No.	A202107010		
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.	TCS-CD004	TCS-CD005	TCS-CD006
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation			
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form 6 for Ceftazidime specifying quantity 5Kg from Harbin Pharmaceutical Group Co., Ltd No. 109 Xuefu Road Nanang District Harbin People Republic of China submitted dated: 03-06-2021
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	
6.	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	Reply
1.	1.5.6	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin. ii. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	**Firm submitted Request for Hold/Withdrawal of Dossier:** **"**We the Citi (Pvt) Ltd. Lahore wish to hold and withdraw our Registeration dossier of Ceftazidime Injection (250mg, 500mg, and 1g) submitted due to some technical issues in dossier compilation."
2.	2.3.A.1	Provide evidence of atomic absorption spectrophotometer	
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.4.2	Detailed analytical procedures for the testing of drug substance by drug product manufacturer shall be provided.	
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	
6.	3.2.S.4.4	• Provide Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture used during product development and stability studies. • Justification of not performing content of Sodium carbonate as recommended by USP monograph.	
7.	3.2.P.1	Applied formulation does not show eq of pentahydrate	
8.	3.2.P.2.2.1	Justify How Pharmaceutical equivalence results are same for 500mg and 250gm	
9.	3.2.P.3.3	In Manufacturing method solution form of injection is prepared . Clarify. Flow diagram for manufacturing of Ceftriaxon submitted.	
10.	3.2.P.2.6	Compatibility with diluent of Cefuroxime submitted. Clarify.	
11.	3.2.P.5.1	Your drug product specifications are not as per USP since many tests recommended by USP are not performed	
12.	3.2.P.5.2	Analytical testing method of different product submitted which are different from USP monograph. Justify why contents of sodium carbonate is not performed in the drug product also	
13.	3.2.P.5.3	Analytical method verification submitted by UV method while USP monograph specify by HPLC.	
14.	3.2.P.5.4	COA's of drug product show different specification than USP and different bacth No than mentioned in stability studies.	
15.	3.2.P.6	Provide COA and evidence of import of Ceftazidime, Delta-3-Isomer RS which is used in the analysis of drug product	
16.	3.2.P.8	Justify how stability results of 03 batches of Accelerated stability studies and real time studies of 500mg and 250mg are same.	

Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off. Registration Board further noted that firm's quota of priority consideration against the new sections will also be deducted for the consideration of instant application.

308.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Address: 3 K.M, Head Balloki Road, phool Nagar Distt, Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34503 dated 29-11-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 1168509716
	The proposed proprietary name / brand name	Citzadime Injection 1g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ceftazidime……. 1g (with Sodium carbonate)
	Pharmaceutical form of applied drug	Parenteral
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime 1g powder for solution for injection by Sandoz Limited of MHRA approved
	For generic drugs (me-too status)	Cefcom 1g of M/s Barrett Hodgson
	GMP status of the Finished product manufacturer	Last GMP inspection conducted on 07-06-2022 and report concludes that firm has currently fair compliance of GMP.
	Name and address of API manufacturer.	Harbin Pharmaceutical Group Co., Ltd General Pharm. Factory No. 109 Xuefu Road Nanang District Harbin People Republic of China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ceftazidime 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 36 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (A20021202, A20021203, A20021204)
	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	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Harbin Pharmaceutical Group Co., Ltd General Pharm. Factory		
API Lot No.	A202107010		
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.	TCS-CD007	TCS-CD008	TCS-CD009
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation			
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form 6 for Ceftazidime specifying quantity 5Kg from Harbin Pharmaceutical Group Co., Ltd No. 109 Xuefu Road Nanang District Harbin People Republic of China submitted dated: 03-06-2021
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	
6.	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	Reply

1.	1.5.6	Valid Drug Manufacturing License issued by the relevant regulatory authority of country of origin. ii. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	**Firm submitted Request for Hold/Withdrawal of Dossier:** **"**We the Citi (Pvt) Ltd. Lahore wish to hold and withdraw our Registeration dossier of Ceftazidime Injection (250mg, 500mg, and 1g) submitted due to some technical issues in dossier compilation."
2.	2.3.A.1	Provide evidence of atomic absorption spectrophotometer	
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.4.2	Detailed analytical procedures for the testing of drug substance by drug product manufacturer shall be provided.	
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	
6.	3.2.S.4.4	• Provide Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture used during product development and stability studies. • Justification of not performing content of Sodium carbonate as recommended by USP monograph.	
7.	3.2.P.1	Applied formulation does not show eq of pentahydrate	
8.	3.2.P.2.2.1	Justify How Pharmaceutical equivalence results are same for 1gm and 250gm	
9.	3.2.P.3.3	In Manufacturing method solution form of injection is prepared . Clarify. Flow diagram for manufacturing of Ceftriaxon submitted.	
10.	3.2.P.2.6	Compatibility with diluent of Cefuroxime submitted. Clarify.	
11.	3.2.P.5.1	Your drug product specifications are not as per USP since many tests recommended by USP are not performed	
12.	3.2.P.5.2	Analytical testing method of different product submitted which are different from USP monograph. Justify why contents of sodium carbonate is not performed in the drug product also	

13.	3.2.P.5.3	Analytical method verification submitted by UV method while USP monograph specify by HPLC.	
14.	3.2.P.5.4	COA's of drug product show different specification than USP and different bacth No than mentioned in stability studies.	
15.		Provide COA and evidence of import of Ceftazidime, Delta-3-Isomer RS which is used in the analysis of drug product	
16.		• Justify how stability results of 03 batches of Accelerated stability studies and real time studies of 1gm and 250mg are same • 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)	

Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off. Registration Board further noted that firm's quota of priority consideration against the new sections will also be deducted for the consideration of instant application.

Case no. 05 Registration applications of categories to be considered on priority

a. Export facilitation

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR-I (EFD) "M/s Genix Pharma Private Limited , Karachi have achieved benchmark OF USD 1,042,800 as defined in the Board's decision during fiscal year 2021-2022. In this regard, please find the (1 molecule) 04 products applications submitted by the firm."

309.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17605 dated 16-06-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 586401314610
	The proposed proprietary name / brand name	AMPRID Tablets 50mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Amisulpride ……..50mg (BP Specification)

	Pharmaceutical form of applied drug	White color, Round shape, Biconvex, Core tablet engraved "GENIX" on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	7's, 10's, 12's, 14's, 20's & 30's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	AMISULPRIDE 50mg TABLETS by Accord-UK Ltd (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets 50mg by Sami Pharmaceutical private limited.
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 15-06-2021 and valid for two (02) years.
	Name and address of API manufacturer.	M/s.Sun Pharmaceutical Industries Ltd **Address:** Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, TamilNadu - 603303, 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 Amisulpride is present in BP. 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 72 months **Accelerated:** 40°C ± 2°C / 75% ± 5%RH for 6 months **Batches:** (PDNAMSFL017, PDNAMSFL018 & PDNAMSFL019)
	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 SOLIAN tablet 50mg (Batch no: 9SS0014) by SANOFI by performing quality tests (Identification, average weight Assay, Disintegration, Dissolution) CDP has been performed against the same brand that

		is SOLIAN tablet 50mg (Batch no: 9SS0014) by SANOFI 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 verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sun Pharmaceutical Industries Ltd		
API Lot No.	AMRNF20062		
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.	21SB(A)-029-01	21SB(A)-030-02	21SB(A)-031-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	23-06-2021	23-06-2021	23-06-2021
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 GMP certificate No# /K Dis. No: 16478/D1/4/2021 issued by Department of Food Safety and Drug Control Administration Government of Tamilnadu India. issued and valid until 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form invoice (invoice# 7000058840) dated: 28-01-2021 cleared by DRAP Karachi office dated 17-02-2021 specifying import 5Kg of Amisulpride (Batch# AMRNF20062)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	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.	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies Submitted by HPLC while B.P specifications are claimed	Analytical method verification studies are submitted for related substances via HPLC. However the assay testing is carried via Titrimetric method, both by the

			API manufacturer and finished product manufacturer.
3.	3.2.P.5.1	Specification mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
4.	3.2.P.5.2	Analytical testing method mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
5.	3.2.P.8	Specifications for Dissolution in section 3.2.P.5.1 are NLT 85% (Q) while in stability studies data specifications are NLT 75% (Q). Clarify	Revise SOP provided in Annexure

Decision: Approved with BP specifications.

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

310.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17606 dated 16-06-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 8318355938
	The proposed proprietary name / brand name	**AMPRID** Tablets 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Amisulpride ……..100mg (BP Specification)
	Pharmaceutical form of applied drug	White color, Round shape, Biconvex, Core tablet engraved "GENIX" on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	7's, 10's, 12's, 14's, 20's & 30's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Solian tablet 100mg by SANOFI (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets 100mg by Sami Pharmaceutical private limited.
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 15-06-2021 and valid for two (02) years.

	Name and address of API manufacturer.	M/s.Sun Pharmaceutical Industries Ltd **Address:** Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, TamilNadu - 603303, 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 Amisulpride is present in BP. 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 72 months **Accelerated:** 40°C ± 2°C / 75% ± 5%RH for 6 months **Batches:** (PDNAMSFL017, PDNAMSFL018 & PDNAMSFL019)
	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 **SOLIAN tablet 100mg** (Batch no: 8NA006) by **SANOFI** by performing quality tests (Identification, average weight Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is **SOLIAN tablet 100mg** (Batch no: 8NA006) by **SANOFI** 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 verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sun Pharmaceutical Industries Ltd
API Lot No.	AMRNF20062
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.	21SB(A)-032-01	21SB(A)-033-02	21SB(A)-034-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	24-06-2021	24-06-2021	24-06-2021
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 GMP certificate No# /K Dis. No: 16478/D1/4/2021 issued by Department of Food Safety and Drug Control Administration Government of Tamilnadu India. issued and valid until 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form invoice (invoice# 7000058840) dated: 28-01-2021 cleared by DRAP Karachi office dated 17-02-2021 specifying import 5Kg of Amisulpride (Batch# AMRNF20062)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	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.	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies Submitted by HPLC while B.P specifications are claimed by drug product manufacturer.	Analytical method verification studies are submitted for related substances via HPLC. However the assay testing is carried via Titrimetric method, both by the API manufacturer and finished product manufacturer.
3.	3.2.P.5.1	Specification mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
4.	3.2.P.5.2	Analytical testing method mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
5.	3.2.P.8	Specifications for Dissolution in section 3.2.P.5.1 are NLT 85% (Q) while in stability studies data specifications are NLT 75% (Q). Clarify	Revise SOP provided in Annexure

Decision: Approved with BP specifications.

	• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
311.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17524 dated 15-06-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 22509764726
	The proposed proprietary name / brand name	**AMPRID** Tablets 200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Amisulpride ……..200mg (BP Specification)
	Pharmaceutical form of applied drug	White color, Round shape, Biconvex, Core tablet engraved "GENIX" on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	7's, 10's, 12's, 14's, 20's & 30's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Solian tablet 200mg by SANOFI (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets 200mg by Sami Pharmaceutical private limited.
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 15-06-2021 and valid for two (02) years.
	Name and address of API manufacturer.	M/s.Sun Pharmaceutical Industries Ltd **Address:** Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, TamilNadu - 603303, 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 **Amisulpride** is present in BP. 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 72 months **Accelerated:** 40°C ± 2°C / 75% ± 5%RH for 6 months **Batches:** (PDNAMSFL017, PDNAMSFL018 & PDNAMSFL019)
	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 SOLIAN tablet 200mg (Batch no: 3Y078) by SANOFI by performing quality tests (Identification, average weight Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is SOLIAN tablet 200mg (Batch no: 3Y078) by SANOFI 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 verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Sun Pharmaceutical Industries Ltd		
API Lot No.	AMRNF20062		
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.	21SB(A)-035-01	21SB(A)-036-02	21SB(A)-037-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	24-06-2021	24-06-2021	24 -06-2021
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 GMP certificate No# /K Dis. No: 16478/D1/4/2021 issued by Department of Food Safety and Drug Control Administration Government of Tamilnadu India. issued and valid until 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form invoice (invoice# 7000058840) dated: 28-01-2021 cleared by DRAP Karachi office dated 17-02-2021 specifying import 5Kg of Amisulpride (Batch# AMRNF20062)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	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.	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies Submitted by HPLC while B.P specifications are claimed by drug product manufacturer.	Analytical method verification studies are submitted for related substances via HPLC. However the assay testing is carried via Titrimetric method, both by the API manufacturer and finished product manufacturer.
3.	3.2.P.5.1	Specification mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
4.	3.2.P.5.2	Analytical testing method mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
5.	3.2.P.8	Specifications for Dissolution in section 3.2.P.5.1 are NLT 85% (Q) while in stability studies data specifications are NLT 75% (Q). Clarify	Revise SOP provided in Annexure

Decision: Approved with BP specifications.

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

312.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited

		44-45B Korangi creek road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17525 dated 15-06-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 21427318529
	The proposed proprietary name / brand name	**AMPRID** Tablets 400mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amisulpride ……..400mg (BP Specification)
	Pharmaceutical form of applied drug	White color, Round shape, Biconvex, Film Coated tablet engraved "GENIX" on one side and plain on other side
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	7's, 10's, 12's, 14's, 20's & 30's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	**Solian** tablet 400mg by SANOFI (MHRA Approved)
	For generic drugs (me-too status)	Ampisol Tablets 400mg by Sami Pharmaceutical private limited.
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 15-06-2021 and valid for two (02) years.
	Name and address of API manufacturer.	M/s.Sun Pharmaceutical Industries Ltd **Address:** Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, TamilNadu - 603303, 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 **Amisulpride** is present in BP. 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 72 months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Batches:** (PDNAMSFL017, PDNAMSFL018 & PDNAMSFL019)
	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 SOLIAN tablet 400mg (Batch no: 5Q0035) by SANOFI by performing quality tests (Identification, average weight Assay, Disintegration, Dissolution) CDP has been performed against the same brand that is SOLIAN tablet 400mg (Batch no: 5Q0035) by SANOFI 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 verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sun Pharmaceutical Industries Ltd		
API Lot No.	AMRNF20062		
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.	21SB(A)-038-01	21SB(A)-039-02	21SB(A)-040-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	23-06-2021	23-06-2021	23-06-2021
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 GMP certificate No# /K Dis. No: 16478/D1/4/2021 issued by Department of Food Safety and Drug Control Administration Government of Tamilnadu India. issued and valid until 31-12-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form invoice (invoice# 7000058840) dated: 28-01-2021 cleared by DRAP Karachi office dated 17-02-2021 specifying import 5Kg of Amisulpride (Batch# AMRNF20062)

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

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	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.	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies Submitted by HPLC while B.P specifications are claimed by drug product manufacturer.	Analytical method verification studies are submitted for related substances via HPLC. However the assay testing is carried via Titrimetric method, both by the API manufacturer and finished product manufacturer.
3.	3.2.P.5.1	Specification mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
4.	3.2.P.5.2	Analytical testing method mentioned for Assay is 90% - 110% while specification claimed are BP which states Assay limits 95%-105%	The Specifications are updated as per B.P i.e 95%- 105%.Specification are attached along with the updated Product Development Document as Annexure
5.	3.2.P.8	Specifications for Dissolution in section 3.2.P.5.1 are NLT 85% (Q) while in stability studies data specifications are NLT 75% (Q). Clarify	Revise SOP provided in Annexure

Decision: Approved with BP specifications.

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

b. Import applications of priority categories defined by Registration Board in its 257th meeting

i. Human

a) Deferred case:

313.	Name, address of Applicant / Importer	M/s Schazoo Pharmaceuticals Laboratories (Pvt) Ltd., Sheikhupura.
	Details of Drug Sale License of importer	License No: 05-354-0076-059245D Address: Kalawala stop 20-KM Lahore Jaranwala Road Tehsil Sharaqpur Sharif District Sheikhupura. Address of Godown: NA Validity: 25-09-2022 Status: License to sell drugs as distributor
	Name and address of marketing authorization	BDR Pharmaceutical International Pvt.Ltd

	holder (abroad)	R.S.NO.578, NR EFFLUENT CHANNEL ROAD, VILLAGE:-LUNA, TAL: PADRA,DIST-VADODARA-391 440
	Name, address of manufacturer(s)	BDR Pharmaceutical International Pvt.Ltd R.S.NO.578, NR EFFLUENT CHANNEL ROAD, VILLAGE:-LUNA, TAL: PADRA,DIST-VADODARA-391 440
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# MFG/WHO-COPP/BDR Pharma/2021/069340) Valid up to 15-12-2022 by , Food and Drug control administration Gujrat state india **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP and Periodicity of inspections is mentioned Yearly. Section of Tablet Cytotoxic mentioned in Eudra GMP certificate
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from M/s BDR Pharmaceuticals International Private Limited 407/408, Sharda Chambers, New Marine Lines Mumbai., Maharashtra, India. The letter specifies that the manufacturer appoints M/s Schazoo Pharmaceuticals Laboratories (Pvt) Ltd., Sheikhupura to register their products in Pakistan. Issued on 23-08-2021
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 10475 dated: 25-04-2022
	Details of fee submitted	PKR 150,000/- deposit Slip # 81027502940
	The proposed proprietary name / brand name	Kapcitabine Tablet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Capecitabine USP…… 500mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Anti-Neoplastic (Colorectal) WHO ATC code: (L01BC06) (capecitabine) is a nucleoside metabolic inhibitor with antineoplastic activity indicated for: • Adjuvant Colon Cancer – Patients with Dukes' C colon cancer. • Metastatic Colorectal Cancer– First-line as monotherapy when treatment with fluoropyrimidine therapy alone is preferred

		• Metastatic Breast Cancer– In combination with docetaxel after failure of prior anthracyclinecontaining therapy – As monotherapy in patients resistant to both paclitaxel and an anthracycline-containing regimen
	Reference to Finished product specifications	USP
	Proposed Pack size	12 Alu PVC blisters of 10 tablets each packed in a monocarton along with pack insert.
	Proposed unit price	30,000/Pack
	The status in reference regulatory authorities	XELODA® 500mg of USFDA approved.
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance..
	Name, address of drug substance manufacturer	BDR Life Sciences Private Limited Address: R.S.No.578, Near Effluent Channel At & post- Luna, Taluka-padra, City- Luna 391 440 Dist. Vadodara, Gujrat Stat, India
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 30°C ± 2°C / 75 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months Batches: (CPZO17001M, CPZO17002M, CPZO17003M)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted CDP with of XELODA (Reference Drug Product)
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Alu-PVC blister

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 75% ± 5% for 12 months. Batches:((ECKAN2117, ECKAN2217, ECKAN0418)

Remarks of Evaluator: Fee submitted on DML

S.No	Section	Shortcomings Communicated
1.	1.3.4	• Address on DSL mentioned is M/s Schazoo Pharmaceuticals (Pvt) Ltd., Sheikhupura while, address in section 1.3.1 and on letter of Authorization, M/s Schazoo Pharmaceuticals Laboratories (Pvt) Ltd mentioned. Clarification is required. • Submit Valid DSL.
2.	3.2.P.2.2.1	• Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed. • Submit CDP in details with details of Reference product against which CDP was conducted and its origin.

Previous Decision (M-324): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply :

S.NO	Section	Shortcomings Communicated	Reply
1.	1.3.4	• Address on DSL mentioned is M/s Schazoo Pharmaceuticals (Pvt) Ltd., Sheikhupura while, address in section 1.3.1 and on letter of Authorization, M/s Schazoo Pharmaceuticals Laboratories (Pvt) Ltd mentioned. Clarification is required. • Submit Valid DSL.	The correct/complete name of the applicant is M/s The Schazoo Pharmaceutical Laboratories (Pvt) Ltd. Kapecitabine Tablet dossier is imported product and it is applied on the basis of DSL. The name of applicant is M/s The Schazoo Pharmaceutical Laboratories (Pvt) Ltd. Copy of renewal of DSL receipt attached.
2.	3.2.P.2.2.1	• Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed. • Submit CDP in details with details of Reference product against which CDP was conducted and its origin.	• Pharmaceutical Equivalence against Xeloda 500mg of F.Hoffmann-La Roche Ltd, Switerzerland conducted and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product are submitted. • CDP in Water,).1 N HCl pH (1.0-1.2) & Acetate buffer 4.5pH and Phosphate Buffer (pH 6.8) with Xeloda manufactured by Roche Germany

Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad. Firm shall submit full fee of registration for application on DSL, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

314.	Name, address of Applicant / Importer	M/s Hakimsons Private Limited., Hakimsons House, A-58/B, S.I.T.E, Manghopir Road, Karachi-75700, Pakistan.
	Details of Drug Sale License of importer	**License No:** 001 No. DHOKW (Drugs)/-0431

		Address: A-58/B, S.I.T.E, Karachi **Address of Godown:** NA **Validity:** 21-08-2022 **Status:** Drug license by the way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Eugia Pharma Specialities Limited. Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Medchal, Telangana, 500101, India.
	Name, address of manufacturer(s)	M/s Eugia Pharma Specialities Limited. Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Medchal, Telangana, 500101, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted Original Legalized CoPP (Certificate#2850/STORES/2020-38) issued by Drugs Control Administration, Government of Telangana, India for ENZASTIK Capsules 40mg (Enzalutamide). CoPP confirms facilities and operations conforming to GMP as recommended by the World Health Organization. The certificate is valid till 28.11.2021. **GMP certificate:** The firm has submitted copy of GMP certificate for M/s Eugia Pharma Specialities Ltd. India issued by Drugs control Administration, Government of Telangana, India. The certificate is valid till 28-11-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted a copy of letter of authorization from M/s Aurobindo Pharma Limited, plot No.2, Maitri Vihar, Ameerpet, Hyderabad. According to the letter, the firm has appointed "M/s Hakimsons Pvt. Ltd," with principal place of business at A-58/B, S.I.T.E, Manghopir Road, Karachi as its Exclusive Distributor for the territory of Islamic Republic of Pakistan. The letter was issued on 10-12-2020 and it is valid for a period of five years. **The applicant has submitted notarized copy of letter clarifying the relationship between Eugia pharma specialities Limited and Aurobindo Pharma Ltd.** Eugia pharma specialities Limited is wholly owned subsidiary company of Aurobindo Pharma Limited with registered office address "Plot No.2, Maitrivihar, Ameerpet, Hyderabad, Telanagana State, India. Eugia pharma specialities Limited, with manufacturing site address "survey no. 550, 551 & 552, kolthur village, shamirpet Mandal, Medchal -Malkagiri District, Telangana, India, manufactures oncology & Hormonal products and is one of the manufacturing facilities associated with Aurobindo Pharma Limited.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 23873 dated: 31-08-2021
	Details of fee submitted	PKR 100,000/- dated :04-02-2021
	The proposed proprietary name / brand name	**ENZASTIK – 40 Capsules 40mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Enzalutamide…….40mg
	Pharmaceutical form of applied drug	Soft gelatin capsule (Anti-neoplastic Agent)
	Pharmacotherapeutic Group of (API)	L02BB ; Anti-androgens XTANDI is an androgen receptor inhibitor indicated for the treatment of patients with: • castration-resistant prostate cancer. • Metastatic castration-sensitive prostate cancer.
	Reference to Finished product specifications	In house
	Proposed Pack size	4 x 28's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	XTANDI (enzalutamide) capsules 40mg **(USFDA** Approved).
	For generic drugs (me-too status)	----
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Name, address of drug substance manufacturer	M/s Laurus Labs Limited, Plot No. 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531021 Andhra Pradesh, India Tel: +91-891-3061222 Fax: +91-891-3061270
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 03 batches of API at accelerated as well as real time conditions 40 ± 2° C / 75 ± 5% RH . The real time stability data is conducted at 25 ± 2° C/60 ± 5%RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has submitted physicochemical evaluation of **XTANDI 40 mg Capsules manufactured by Astellas Pharma, Europe B.V, Netherlands (Reference Drug Product)** and also submitted finished product evaluation of Enzalutamide Capsules 40 mg by **Eugia Pharma Specialties Limited (Proposed Generic Product) (B.No: EN4017003-B)**
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	PVC/PVDC/Aluminum foil blister pack
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 06 months. The real time stability study data is conducted at 30ºC ±2ºC / 75% ± 5% RH. The real time stability study data of 03 batches is for 24months.

Evaluation by PEC:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Submitted
2.	3.2.P.3.5	process validation reports including the protocols and results for critical process steps mentioned in 2.3.P.3.4 / 3.2.P.3.4 shall be provided.	All critical quality attributes mentioned in 2.3.P.3.4/3.3.P.3.4 are covered in process validation reports except "Gelatin shell weight and Gelatin gross weight of capsule" are not covered in process validation report. However, these are regularly monitored as in process checks at initial and every 30 minutes and results are reported in batch manufacturing record.
3.	3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" 0.1N HCl/ 0.3% CTAB,	Our product is a dosage form of soft gelatin capsule formulation. Gelatin cross-linking is a common problem of gelatin capsule, which is typically triggered by catalytic amounts of aldehydes and /or from exposure to high temperature and humidity. This impact is

<table>
<tr><td></td><td></td><td>whereas submitted specifications declare the dissolution limits as “NLT 75% in 30 minutes” . Justify the variation in time point of dissolution.</td><td>commonly seen in stability testing and results in lower and/or incomplete dissolution invitro. Enzymes like pepsin and pancreatin act by cleavage of peptide bonds present in cross- linked gelatin and there by resulting in release of content from capsule
Dissolution method for drug product (Enzalutamide capsule 40mg) includes both Tier-I media (with out enzymes) and Tier-II media [ith inclusion of enzymes i.e., Pepsin added in 0.3% CTAB(cetyl trimethyl ammonium bromide) in 0.1N HCl]. In the instance of drug product failing to meet the acceptance criteria in Tier-I due to gelatin cross-linking , Tier-II method would be adopted.
Since the test product shows the cross linking tendency, we have adopted the dissolution method bot Tier-I and Tier-II in the analytical testing methodology.. The tier-II dissolution testing for cross-linked capsules involves two steps:
1) Pre-treatment
2) After Pre-treatment (main treatment)
In first step pre-treatment the cross-linked capsules were subjected to exposure (pre-soaking) to pepsin enriched media (450ml)for 10 minutes . After pre-treatment remaining pre-warmed plain 0.1N HCl/ 0.3% CTAB (without any pepsin) is added to makeup the final volume to 900ml. therefore the representation of dissolution time point [Q time point in Tier-I media is 30 minutes, which includes 10 minutes of pre-treatment step and remaining 20 minutes of main treatment in final volume.
Hence based on the above dissolution testing discussion and considering the higher disintegration time allowed for soft gelatin capsule, the following dissolution limits are proposed for release and stability shelf life testing of Enzalutamide capsule.
<table><tr><td rowspan="2">Test</td><td colspan="2">Adopted dissolution Limits</td></tr><tr><td>Release</td><td>Shelf life</td></tr><tr><td>Dissolution (%)</td><td>NLT 75% Q in 30 minutes</td><td>NLT 75% Q in 30 minutes</td></tr></table></td></tr>
<tr><td>4.</td><td>3.2.P.8</td><td>From submitted stability data for product it is not evident that dissolution testing conducted either on Tier-1, or Tier-2 or both.</td><td>All batches were tested with Tier-1 method up to 12 months and from 18 months station batches are tested with Tier-2 method. Stability data results with note “ Results pass at Tier-2 stage” are enclosed.</td></tr>
<tr><td colspan="4">Previous Decision: Deferred for following:
• Details of Reference Drug Product against which pharmaceutical equivalence and CDP studies were performed.
• Clarification that Gelatin shell weight and Gelatin gross weight of capsule” are not monitored in process validation. (M- 317 RB)</td></tr>
<tr><td colspan="4">Response of firm:</td></tr>
<tr><td colspan="2">Details of Reference Drug Product against which pharmaceutical equivalence and CDP studies were performed.</td><td colspan="2">The details of reference used against pharmaceuticals equivalence and CDP studies are:
XTANDI 40 mg Capsules
Manufactured by Astellas Pharma, Europe B.V, Netherlands.
Batch No. 15 D11/15</td></tr>
<tr><td colspan="2">Clarification that Gelatin shell weight and Gelatin gross weight of capsule” are not monitored in process validation.</td><td colspan="2">Please be informed that all critical quality attributes mentioned in 2.3.P.3.4/3.3.P.3.4 are covered in process validation reports except “Gelatin shell weight and Gelatin gross weight of capsule” are not</td></tr>
</table>

	covered in process validation report. However, these are regularly monitored as in process checks at initial and every 30 minutes and results are reported in batch manufacturing record Please find enclosed herewith the pages of in process control parameters along with in process check record of the BMR for your ready reference. **[Firm submitted BMR pages of 03 Batches (Batch No# EN4017001, EN4017002 and EN4017003) in which In process Control parameters, where frequency(During start up and every 30 minutes alternate by production and QA) and limits for Gelatin shell weight and Gelatin gross weight of capsule checks is mentioned. Moreover they submitted sheets for Start up checks by production and by QA for Gelatin shell weight and gross weight of capsule and In process check record every 30 minutes alternate by production and QA for Gelatin shell weight and gross weight of capsule]**

Previous Decision (M-320): Deferred for following points:

- Evidence of requisite manufacturing facility i.e. soft gelatin cytotoxic as provided document does not mention about dedicated facility.
- Submission of fee of Rs. 7,500 for revision of specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

S.NO	Reason of deferment	Reply
1.	Evidence of requisite manufacturing facility i.e. soft gelatin cytotoxic as provided document does not mention about dedicated facility.	GMP certificate No # 4277/STORES/2022 DATED 28-11-2022 for M/s Eugia Pharma Specialities Limited. Survey No. 550, 551 & 552, Kolthur Village, Shamirpet Mandal, Medchal-Malkajgiri, District Medchal, Telangana, 500101, India in which Soft & Hard Gelatin Capsules for Oncology products mentioned.
2.	Submission of fee of Rs. 7,500 for revision of specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Revision of specification from "Inhouse" to Innovator specification with a submission of fee of Rs: 7500/- Deposit slip# 8254451896 , Dated: 17-01-2023

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

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, address of Applicant / Importer	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd, Pakistan
	Details of Drug Sale License of importer	License No: 05-354-0076-059245D Address: Kalalwala stop 20-KM Lahore Jaranwala Road Tehsil Sharaqpur Sharif District Sheikhupura. Address of Godown: NA Validity: 25-09-2022 Status: Complete Renewal: Firm has applied for renewal on 22-09-2022.
	Name and address of marketing authorization holder (abroad)	Bdr Pharmaceutical International Pvt.Ltd R.S.No.578, Nr Effluent Channel Road, Village:-Luna, Tal: Padra,Dist-Vadodara-391 440
	Name, address of manufacturer(s)	Bdr Pharmaceutical International Pvt.Ltd R.S.No.578, Nr Effluent Channel Road, Village:-Luna, Tal: Padra,Dist-Vadodara-391 440
	Name of exporting country	India

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP ((No. MFG/WHO-COPP/BDR PHARMA/2021/069343) by Food and Drug Control administartion Gujarat State India. **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP and Periodicity of inspections is mentioned Yearly. **valid till 15-12-2022** (Section of Hard shell Capsule cytotoxic mentioned in GMP certificate)
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from BDR Pharmaceuticals international Pvt. Ltd. The letter species that the manufacturer appoints M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3891 dated: 10-02-2022
	Details of fee submitted	PKR 75,000/- deposit Slip # 067677943
	The proposed proprietary name / brand name	ENZALUTA Capsules 40mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enzalutamide…….....40mg
	Pharmaceutical form of applied drug	Hard Gelatin capsule
	Pharmacotherapeutic Group of (API)	Androgen receptor inhibitors
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	Enzalutamide Capsules 40 mg packed in Alu-PVC blister containing 28 capsules each as primary pack. One such blister packed in a carton along with pack insert.
	Proposed unit price	12 x 10's :As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	…
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	BDR Life Sciences Private Limited R.S.No.578, Near Effluent Channel, At & Post - Luna, Taluka - Padra, City – Luna 391 440 Dist. Vadodara, Gujarat State, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 30°C ± 2°C / 75 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C±2°C and 75%±5% for 6 months Batches: (EZZN170001, EZZN170002, EZZN170003)
	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	Comparison have been established against **XTANDI 40mg Soft Gelatin Capsule** by performing quality tests (Identification, Assay, Uniformity of dosage units, Dissolution, , Disintegration Time).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu-Pvc Blisters
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 75% ± 5% for 36months. Batches: (BENAN0217, BENAN0317, BENAN0417)

Remarks of Evaluator: Fee submitted on DML

S.No	Section	Shortcomings Communicated	
1.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (Hard gelatin Capsule) in any one of the reference regulatory authority specified by Registration Board in its 275th meeting, for further Evaluation of application.	Firm submitted Bioequivalence study in reply against XTANDI 40mg Soft Gelatin Capsule of Astellas Pharma US,

Comparison		
S.NO	**XTANDI 40mg Soft Gelatin Capsule of Astellas Pharma US,**	**ENZALUTA Capsules 40mg of Bdr Pharmaceutical International Pvt.Ltd**

1.	**Description:** XTANDI is provided as liquid-filled soft gelatin capsules	White to off white Granular Powder filled in Hard gelatin Capsule shell
2.	**Compostion:** Caprylocaproyl Polyoxylglycerides NF Butylated Hydroxyanisole NF Butylated Hydroxytoluene	**Compostion:** Acetone Caprylocaproyl Polyoxyl- 8 glycerides (Labrasol ALF) Colloidal silicon Dioxide Microcrystalline cellulose
3.	**Analytical testing method:** **Dissolution:** USP Apparatus II Paddle speed: 50 rpm Volume/Temp: 900 ml / 37o C Tier-1: 0.1N HCl/0.3% CTAB, Tier-2: 0.1N HCl/ 0.3% CTAB/pepsin; Q= % at 15 minutes	**Dissolution:** USP Apparatus II Paddle speed: 50 rpm Volume/Temp: 900 ml / 37o C .1N HCl/0.3% CTAB, Additional test : Tier-2: 0.1N HCl/ 0.3% CTAB/pepsin; Q= % at 30 minutes

Previous Decision (M-324): Deferred for evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (Hard gelatin Capsule) in any one of the reference regulatory authority specified by Registration Board in its 275th meeting.

Reply: We, BDR Pharmaceutical International Pvt. Ltd, inform that Enzalutamide Capsules 40mg, is registered by us in the following countries. In addition, we also hold a valid manufacturing and marketing authorization in the country of origin (India).

Sr No.	Generic Name of the Product	Country	Issued	Expires	Registration No.	Type
1	Enzalutamide Capsules 40mg	Bolivia	03-02-2020	02-02-2025	II-72783/2020	Initial
2	Enzalutamide Capsules 40mg	Sri Lanka	29-04-2019	28-04-2021	M005794	Initial
3	Enzalutamide Capsules 40mg	Kazakhstan	05-06-2021	05-06-2026	RK-LS-5# 025030	Initial
4	Enzalutamide Capsules 40mg	Ecuador	18-03-2021	18-03-2026	6037-MEE-0321	Initial
5	Enzalutamide Capsules 40mg	Kenya	19-04-2021	19-04-2022	H2021/CTD5995 /1872ER	Initial
6	Enzalutamide Capsules 40mg	Philippines	18-02-2022	18-02-2027	DRP-11260	Initial

(***However these are not reference agencies specified by Registration Board in its 275th meeting.)***

Decision: Deferred for evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (Hard gelatin Capsule) in any one of the reference regulatory authority specified by Registration Board in its 275th meeting.

Agenda of Evaluator PEC-IX

New Cases of Form-5

316.	Name and address of manufacturer/ Applicant	M/s. Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-K, industrial estate, Hayatabad, Peshawar (contract giver) (DML No.000386) Contract with M/s. Mediate Pharmaceutical (pvt.) ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi (Contract Acceptor) (DML No.000167) Dry Powder Injectable (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	RAKPIME Injection 1gm (IV/IM)
	Composition	Each vial contains; Cefepime HCl with L-Arginine equivalent to Cefepime …..1000mg

	Diary No. Date of R & I & fee	Dy. No. 16203 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0825763 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fourth-generation cephalosporins ATC Code: J01DE01
	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	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	Last inspection of M/s Mediate Pharmaceuticals conducted on 10.05.2022. GMP status is good.
	Remarks of the Evaluator	i. Reference of specifications of finished product 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.**	
317.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342) Contract with M/s. Welmark Pharmaceuticals, Plot No. 122, Block-B, Phase V, Industrial Estate Hattar (Contract Acceptor) (DML No.000614) Section.
	Brand Name + Dosage Form + Strength	PIPRABACT 2g/250mg Injection
	Composition	Each Vial contains; Piperacillin sodium ……2gm Tazobactum sodium……250mg
	Diary No. Date of R & I & fee	Dy. No. 16366 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0797005 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	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	Piperacillin/Tazobactam 2g/0.25g and 4g/0.5g powder for solution for infusion - PL 24598/0012 and PL 24598/0019; UK/H/1209/001-002/DC. MHRA Approved.
	Me-too status	Tanzo 2.25gm Injection Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi.
	GMP status	Last inspection M/s Welmark conducted on 11.11.2021. GMP certificate valid till 10.11.2023 is submitted.
	Remarks of the Evaluator	i. The salt and hydrate is included in strength of API, it requires revision as per products approved in RRA and me-too products along with submission of full fee i.e. Rs. 75000/- ii. Monograph of applied product is available in USP, and in application innovator's specs are applied. Correction is required. iii. Form-5 is filled and signed by contact giver. It is required to be filled and signed by product registration applicant (M/s Trigon Pharm).

		iv. Section approval letter of M/s Wellmark pharma is required.
	Decision: Deferred for following: • **Evidence of approval of required manufacturing facility of "Dry powder injection (penicillin) section" in name of M/s Welmark Pharmaceuticals.** • **Revision of label claim as per innovator product along with fee of Rs. 75000/-. for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Revision of specifications of applied product to Pharmacopoeial specifications.** • **Submission of Form-5 by applicant.**	
318.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342) Contract with M/s. Welmark Pharmaceuticals, Plot No. 122, Block-B, Phase V, Industrial Estate Hattar (Contract Acceptor) (DML No.000614) Section.
	Brand Name + Dosage Form + Strength	Cilinem 250mg/250mg Injection
	Composition	Each Vial contains; Imipenem monohydrate ……250mg Cilastatin sodium……250mg
	Diary No. Date of R & I & fee	Dy. No. 16365 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0797009 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH51
	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	IMIPENEM/CILASTATIN 250MG/250MG AND 500MG/500MG POWDER FOR SOLUTION FOR INFUSION - UK/H/1704/001-002/DC; PL 30306/0112-3 MHRA APPROVED.
	Me-too status	Cilnem500mg Injection Reg. No. 094315 M/s Nicholas Pharmaceuticals Islamabad.
	GMP status	Last inspection M/s Welmark conducted on 11.11.2021. GMP certificate valid till 10.11.2023 is submitted.
	Remarks of the Evaluator	i. The salt and hydrate is included in strength of API, it requires revision as per products approved in RRA and me-too products along with submission of full fee i.e. Rs. 75000/- ii. Monograph of applied product is available in USP, and in application innovator's specs are applied. Correction is required. iii. Form-5 is filled and signed by contact giver. It is required to be filled and signed by product registration applicant (M/s Trigon Pharm). iv. Section approval letter of M/s Wellmark pharma is required. v. The covering letter is of product iminom 500mg/500mg injection whereas details of Cilinem 250mg/250mg are provided. Correction is required.
	Decision: Deferred for following; • **Evidence of approval of required manufacturing facility of "Dry powder injection (Carbapenem) section" in name of M/s Welmark Pharmaceuticals.**	

	• **Revision of label claim as per innovator product along with fee of Rs. 75000/- for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Revision of specifications of applied product to Pharmacopoeial specifications.** • **Submission of Form-5 by the applicant.**	
319.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342) Contract with M/s. Welmark Pharmaceuticals, Plot No. 122, Block-B, Phase V, Industrial Estate Hattar (Contract Acceptor) (DML No.000614) Section.
	Brand Name + Dosage Form + Strength	MERAG 1g Injection (IV)
	Composition	Each Vial Contains; Meropenem as trihydrate (USP) ….1g
	Diary No. Date of R & I & fee	Dy. No. 16363 dated 07.03.2019 Fee paid Rs. 50,000/- vide slip No. 0797007 dated 04.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form 5
	Finished product Specification	**Innovator's Specification.**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 1g Injection Reg. No. 018548 M/s Pfizer Pakistan.
	GMP status	Last inspection M/s Welmark conducted on 11.11.2021. GMP certificate valid till 10.11.2023 is submitted.
	Remarks of the Evaluator	i. Form-5 is filled and signed by contact giver. It is required to be filled and signed by product registration applicant (M/s Trigon Pharm) along with submission of full fee i.e. Rs. 75000/- ii. Section approval letter of M/s Wellmark pharma is required. iii. The monograph of applied product is available in Pharmacopoeia, yet innovator's specifications are applied. Clarification or correction is required.
	Decision: Deferred for following; • **Evidence of approval of required manufacturing facility of "Dry powder injection (Carbapenem) section" in name of M/s Welmark Pharmaceuticals.** • **Revision of specifications of applied product to Pharmacopoeial specifications.** • **Submission of Form-5 by the applicant along with fee of Rs. 75000/- as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
320.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000801) Dry Powder Injectable (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Cefozet Injection 250mg IV
	Composition	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone…..250gm

	Diary No. Date of R & I & fee	Dy. No. 15066 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806295 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 250mg Injection Reg. No. 053144 M/s Lahore Pharma.
	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 satisfactory capacity assessment of manufacturing and testing facility of M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore.	
321.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000801) Dry Powder Injectable (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Cefozet Injection 1gm IV
	Composition	Each vial contains; Ceftriaxone sodium eq. to ceftriaxone…..1gm
	Diary No. Date of R & I & fee	Dy. No. 15068 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806299 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	Rocephin IV/IM Injection 1gm Reg. No. 007014 M/s Martin Dow 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 satisfactory capacity assessment of manufacturing and testing facility of M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore.	
322.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with

		M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000801) Dry Powder Injectable (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Cefozet Injection 500mg IV
	Composition	Each vial contains; Ceftriaxone sodium eq. to ceftriaxone…..500mg
	Diary No. Date of R & I & fee	Dy. No. 15067 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806298 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 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 satisfactory capacity assessment of manufacturing and testing facility of M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore.	
323.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000801) Dry Powder Injectable (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Zectum 1gm Injection
	Composition	Each vial contains; Cefoperazone as sodium…….500mg Sulbactam as sodium……..500mg
	Diary No. Date of R & I & fee	Dy. No. 15064 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806293 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	USP Specifications
	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 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 satisfactory capacity assessment of manufacturing and testing facility of M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore.	
324.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000801) Lyophilized Vials Injectable (General) Section. Section granted vide letter No. F.1-39/2005-Lic (Vol-I) dated 11.04.2017
	Brand Name + Dosage Form + Strength	Esozet 40mg lyophilized Injection
	Composition	Each vial contains; Esomeprazole Sodium Lyophilized equivalent to Omeprazole……40mg
	Diary No. Date of R & I & fee	Dy. No. 15069 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806300 dated 06-03-2019, endorsed on 07.03.2019.
	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. 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. **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore.**	
325.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000801) Lyophilized Vials Injectable (General) Section. Section granted vide letter No. F.1-39/2005-Lic (Vol-I) dated 11.04.2017
	Brand Name + Dosage Form + Strength	Zetaprazole 40mg lyophilized Injection
	Composition	Each vial contains; Omeprazole Sodium Lyophilized equivalent to Omeprazole……40mg
	Diary No. Date of R & I & fee	Dy. No. 15020 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0505014 dated 06-03-2019, endorsed on 07.03.2019.
	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. 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. **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. MTI medical (Pvt.) ltd plot No. 586-587, Sunder Industrial Estate Raiwind Road, Lahore.**	
326.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. GMP Pharmaceuticals, 28-KM, Sheikhupura Road Lahore. (Contract Acceptor) (DML No.000815) Liquid Injectable Ampoule (General) Section.
	Brand Name + Dosage Form + Strength	Zetfer 100mg/5ml Ampoule
	Composition	Each 5ml ampoule contains; Iron Sucrose complex eq. to Elemental Iron…100mg
	Diary No. Date of R & I & fee	Dy. No. 15059 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806287 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Iron, parenteral preparations ATC Code: B03AC
	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	SUCROFER 20 MG IRON/ML, SOLUTION FOR INJECTION /INFUSION (IRON SUCROSE) - UK/H/6369/001/DC; PL 20568/0083 MHRA APPROVED.
	Me-too status	Pak Rose Injection Reg. No. 079638 M/s GMP Pharmaceuticals, Lahore.
	GMP status	Last GMP inspection conducted on 09.03.2022. GMP certificate valid till 08.03.2025 is submitted.
	Remarks of the Evaluator	
	Decision: Deferred for following: • **Revision of label claim for complete salt from of drug substance as per innovator product along with fee of Rs. 75,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Evidence of availability of atomic absorption spectrophotometer as required by the USP monograph of applied formulation.**	
327.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. GMP Pharmaceuticals, 28-KM, Sheikhupura Road Lahore. (Contract Acceptor) (DML No.000815) Liquid Injectable Ampoule (General) Section.
	Brand Name + Dosage Form + Strength	Zeta-D3 5mg/1ml Injection
	Composition	Each 1ml ampoule contains; Cholecalciferol ……5mg

	Diary No. Date of R & I & fee	Dy. No. 15060 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806288 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Vitamin D Analogue
	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	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 GMP inspection conducted on 09.03.2022. GMP certificate valid till 08.03.2025 is submitted.
	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.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. GMP pharmaceuticals, 28-KM, Sheikhupura Road Lahore.**	
328.	Name and address of manufacturer/ Applicant	M/s. Zeta Pharmaceuticals, plot No. 494-A, Sunder Industrial Estate Lahore (contract giver) (DML No.000818) Contract with M/s. GMP pharmaceuticals, 28-KM, Sheikhupura Road Lahore. (Contract Acceptor) (DML No.000815) Oral dry powder suspension (Cephalosporin)
	Brand Name + Dosage Form + Strength	CEFIZET 100mg/5ml Oral Suspension
	Composition	Each 5ml contains; Cefixime (as trihydrate)….100mg
	Diary No. Date of R & I & fee	Dy. No. 15062 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0806290 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	USP Specifications
	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 GMP inspection conducted on 09.03.2022. GMP certificate valid till 08.03.2025 is submitted.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. GMP pharmaceuticals, 28-KM, Sheikhupura Road Lahore.	
329.	Name and address of manufacturer/ Applicant	M/s Medisave Pharmaceuticals 578-579 Sundar Industrial Estate Sundar Raiwind Road Lahore. (contract giver) (DML No. 000681) Contract with M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection (Penicillin) Section

	Brand Name + Dosage Form + Strength	TAZOSAVE 2.25g (IV)
	Composition	Each Vial Contains; Piperacillin (as piperacillin sodium)…..2g Tazobactam (as tazobactam sodium)….0.25g
	Diary No. Date of R & I & fee	Dy. No. 14983 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 00536169 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form 5 (Contract)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Piperacillin/Tazobactam 2g/0.25g and 4g/0.5g powder for solution for infusion - PL 24598/0012 and PL 24598/0019; UK/H/1209/001-002/DC. MHRA Approved.
	Me-too status	Tanzo 2.25gm Injection Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi.
	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. Latest GMP inspection is required. ii. Cases of Medisave contract with Stallion were deferred in 323rd Meeting of Registration board for capacity verification of M/s Stallion.
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt.) Ltd	
330.	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	PIPRAL-T 4.5gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……4.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.5gm
	Diary No. Date of R & I & fee	Dy.No.13916 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902645 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.
	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection of M/s Global conducted on 19.11.2021. GMP Status is good.

	Remarks of the Evaluator	i. The capacity verification of the firm M/s Global Pharmaceuticals was carried out on 21.10.2022 for following sections; o Dry Powder Injection (Cephalosporin) o Dry Powder Injection (Penicillin) o Dry Powder Injection (Carbapenem)
	Decision: Approved.	
331.	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.
	Brand Name + Dosage Form + Strength	Mero 500mg Injection (IV)
	Composition	Each Vial Contains; Meropenem USP……500mg
	Diary No. Date of R & I & fee	Dy.No.13918 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902642 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 500mg Injection Reg. No. 096203 M/s Pfizer Pakistan.
	GMP status	Last inspection of M/s Global conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	i. Label claim is without consideration of hydrated form of the API. Justification or correction of label claim is required for consideration of hydrated form of API along with submission of requisite fee (full fee) ii. The capacity verification of the firm M/s Global Pharmaceuticals was carried out on 21.10.2022 for following sections; o Dry Powder Injection (Cephalosporin) o Dry Powder Injection (Penicillin) o Dry Powder Injection (Carbapenem)
	Decision: Approved with following label claim; **Each vial contains;** **Meropenem as trihydrate ……500mg** **The firm shall submit fee of Rs. 75000/- for correction/pre-approval change in product label 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 Nimrall Laboratories, Plot No. 24, St. No. SS-3, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.

	Brand Name + Dosage Form + Strength	Mero 1g Injection (IV)
	Composition	Each Vial Contains; Meropenem USP……1g
	Diary No. Date of R & I & fee	Dy.No.13917 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902641 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 1g Injection Reg. No. 096204 M/s Pfizer Pakistan.
	GMP status	Last inspection of M/s Global conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	i. Label claim is without consideration of hydrated form of the API. Justification or correction of label claim is required for consideration of hydrated form of API along with submission of requisite fee (full fee) ii. The capacity verification of the firm M/s Global Pharmaceuticals was carried out on 21.10.2022 for following sections; o Dry Powder Injection (Cephalosporin) o Dry Powder Injection (Penicillin) o Dry Powder Injection (Carbapenem)
	Decision: Approved with following label claim; **Each vial contains;** **Meropenem as trihydrate ……1g** **The firm shall submit fee of Rs. 75000/- for correction/pre-approval change in product label 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. Horizon Healthcare (pvt.) Ltd. Plot No. 35-A, Small industrial estate Taxila (Contract Giver) (DML No. 000856) Contract with M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore. (Contract Acceptor) (DML No.000590) (General) Section.
	Brand Name + Dosage Form + Strength	FLOXA-H 400mg/250mL Infusion
	Composition	Each 250ml vial contains; Moxifloxacin (as hydrochloride)….400mg
	Diary No. Date of R & I & fee	Dy. No. 14974 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 1900218 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	Type of Form	Form-5
	Finished product Specification	**NovaMed Specifications.**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Avelox 400 mg/250 ml solution for infusion MHRA Approved.
	Me-too status	Avelox Infusion Reg. No. 030851

		M/s Bayer Pakistan (Pvt.) Ltd. Kot Lakhpat.
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. Evidence of manufacturing facility of 250mL liquid vail at M/s Novamed is required. ii. In response to similar product application the firm M/s Genetics Pharma vide letter No. GP-024/23 dated 06.02.2023 has submitted evidence of vial filling machine having capacity to fill and seal vials of 100ml to 300ml volume. M/s Novamed is already manufacturing X-Lox infusion 400mg/250ml.
	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.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
334.	Name and address of manufacturer/ Applicant	M/s. Horizon Healthcare (pvt.) Ltd. Plot No. 35-A, Small industrial estate Taxila (Contract Giver) (DML No. 000856) Contract with M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore . (Contract Acceptor) (DML No.000590) (General) Section.
	Brand Name + Dosage Form + Strength	HOX-L 400mg/200mL Infusion
	Composition	Each 200ml infusion bag contains; Linezolid …….. 400mg
	Diary No. Date of R & I & fee	Dy. No. 14969 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 1900216 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antibacterials. ATC Code: J01XX08
	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	Could not be found
	Me-too status	Nezkil 400 mg Infusion, Reg. No. 048803 M/s S.J. & G. Fazul Ellahi (Pvt.) Ltd. Karachi
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. Evidence of manufacturing facility of 200mL infusion bag at M/s Novamed is required. ii. In response to similar product application the firm M/s Genetics Pharma vide letter No. GP-024/23 dated 06.02.2023 has submitted evidence of vial filling machine having capacity to fill and seal vials of 100ml to 300ml volume. M/s Novamed is already manufacturing X-Lox infusion 400mg/250ml. iii. Evidence of 400mg/200ml pack approval in RRA is required.
	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.**	

	• **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
335.	Name and address of manufacturer/ Applicant	M/s. Horizon Healthcare (pvt.) Ltd. Plot No. 35-A, Small industrial estate Taxila (Contract Giver) (DML No. 000856) Contract with M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore . (Contract Acceptor) (DML No.000590) (General) Section.
	Brand Name + Dosage Form + Strength	HOX-L 600mg/300mL Infusion
	Composition	Each 300ml infusion bag contains; Linezolid …….. 600mg
	Diary No. Date of R & I & fee	Dy. No. 14970 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 1900217 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other antibacterials. ATC Code: J01XX08
	Type of Form	Form-5
	Finished product Specification	**NovaMed Specifications.**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Zyvox 2 mg/ml solution for infusion, 300 ml infusion bags contain 600 mg linezolid. MHRA Approved
	Me-too status	Nezkil 600 mg Infusion, Reg. No. 048804 M/s S.J. & G. Fazul Ellahi (Pvt.) Ltd. Karachi
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. Evidence of manufacturing facility of 300mL liquid infusion bag at M/s Novamed is required. ii. In response to similar product application the firm M/s Genetics Pharma vide letter No. GP-024/23 dated 06.02.2023 has submitted evidence of vial filling machine having capacity to fill and seal vials of 100ml to 300ml volume. M/s Novamed is already manufacturing X-Lox infusion 400mg/250ml.
	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.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
336.	Name and address of manufacturer/ Applicant	M/s. Horizon Healthcare (pvt.) Ltd. Plot No. 35-A, Small industrial estate Taxila (Contract Giver) (DML No. 000856) Contract with M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore . (Contract Acceptor) (DML No.000590) Oral Dry Powder (General) Section.
	Brand Name + Dosage Form + Strength	MICROX-H 250mg/5mL Powder for oral suspension
	Composition	Each 5ml contains; Ciprofloxacin HCl eq to Ciprofloxacin (USP)..250mg
	Diary No. Date of R & I & fee	Dy. No. 14968 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 1900215 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones

		ATC Code: J01MA02
	Type of Form	Form-5
	Finished product Specification	**In house Specifications.**
	Pack size & Demanded Price	60ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cipro 250mg/5ml USFDA Approved.
	Me-too status	Novidate 250mg Dry Powder for suspension Reg No. 047142 M/s Sami Pharma
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	The innovator product approved in RRA does not use HCl salt of Ciprofloxacin and they are using a special diluent for reconstitution. Clarification or correction along with fee of Rs. 75000/- is required.
	Decision: Registration Board deferred the applications for further deliberation regarding requirement for the diluent for applied formulation. **The registration Board 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.**	
337.	Name and address of manufacturer/ Applicant	M/s. Horizon Healthcare (pvt.) Ltd. Plot No. 35-A, Small industrial estate Taxila (Contract Giver) (DML No. 000856) Contract with M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore. (Contract Acceptor) (DML No.000590) Oral Dry Powder (General) Section.
	Brand Name + Dosage Form + Strength	MICROX-H 125mg/5mL Powder for oral suspension
	Composition	Each 5ml contains; Ciprofloxacin HCl eq to Ciprofloxacin (USP)……125mg
	Diary No. Date of R & I & fee	Dy. No. 14976 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 1900214 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA02
	Type of Form	Form-5
	Finished product Specification	**Inhouse Specifications.**
	Pack size & Demanded Price	60ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Novidate 125mg/5ml Dry Powder for suspension Reg No. 067166 M/s Sami Pharma
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	Evidence of product approval in RRA is required.
	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.	
338.	Name and address of manufacturer/ Applicant	M/s. Sigma Pharma International (Pvt.) Ltd. Plot No. E-50, North Western Industrial Zone, Bin Qasim, Karachi (DML No. 000804) Tablet (General) Section.

	Brand Name + Dosage Form + Strength	NOVOMIT 10mg/10mg Delayed Release Tablet
	Composition	Each delayed release film coated tablet contains; Doxylamine succinate (USP)…..10mg Pyridoxine HCl (USP)……10mg
	Diary No. Date of R & I & fee	Dy. No. 25245 dated 19.02.2017. Fee paid Rs. 20,000/- vide Slip No. 0741983 dated 14-12-2017, endorsed on 19.12.2017. Duplicate dossier: Dy. No. 37507 dated 22.12.2022
	Pharmacological Group	Aminoalkyl ethers, doxylamine, combinations. ATC Code: R06AA59
	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	Xonvea 10 mg/10 mg gastro-resistant tablets (doxylamine succinate and pyridoxine hydrochloride) - PL 16853/0147 MHRA Approved.
	Me-too status	Nausidox 10mg/10mg Tablet. Reg. No. 076292 M/s OBS Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 06.07.2022. GMP status is good. GMP certificate valid till 05.07.2024 is submitted.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of bi-layer tablet compression machine along with IP,OQ & PQ reports.	
339.	Name and address of manufacturer/ Applicant	M/s. Bio-Mark Pharmaceuticals Plot 527, Sunder Industrial Estate, Lahore (Contract Giver) (DML No. 000863) Contract with M/s. Dyson Research Laboratories, 28-KM, Ferozpur Road, Lahore (Contract Acceptor) (DML No. 000559).. (Contract Acceptor) Tablet (hormone) Section.
	Brand Name + Dosage Form + Strength	BIO-PROGYNOVA 2mgTablets
	Composition	Each sugar coated tablet contains; Estradiol valerate…..2mg Norgestrel…….0.5mg
	Diary No. Date of R & I & fee	Dy. No. 10886 dated 05.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0849873 dated 01-03-2019, endorsed on 04.03.2019. Duplicate dossier: Dy. No. 596 dated 06.01.2023
	Pharmacological Group	Progestogens and estrogens, sequential preparations ATC Code: G03FB01
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	21's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cyclo-Progynova® 2mg (Sugar coated) White Tablets 2mg oestradiol valerate Pale Brown Tablets 500 micrograms norgestrel 2mg oestradiol valerate MHRA Approved.
	Me-too status	Progyluton tab Reg No. 012367 M/s Medipharm Lahore (bayer)
	GMP status	Not proivded
	Remarks of the Evaluator	i. The innovator is manufacturing pack of 21 tablets, 11 out of 21 tablets contain only oestradiol valerate 2mg (white tablets) and 10 tablets contain 500mcg norgestrel along with 2mg oestradiol

		valerate (brown tablets). Combination of 2 different formulations is not depicted in applied formulation. Clarification is required. ii. Provide updated GMP status of M/s Dyson
	Decision: Deferred for submission of manufacturing and testing details and revised label claim as per innovator product along with fee of Rs. 75000/- as per No.F.7-11/2012-B&A/DRAP dated 07-05-2021 notification.	
340.	Name and address of manufacturer/ Applicant	M/s. Bio-Mark Pharmaceuticals Plot 527, Sunder Industrial Estate, Lahore (Contract Giver) (DML No. 000863) Contract with M/s. Dyson Research Laboratories, 28-KM, Ferozpur Road, Lahore (Contract Acceptor) (DML No. 000559).. (Contract Acceptor) Tablet (hormone) Section.
	Brand Name + Dosage Form + Strength	Markgest 100mg Vaginal Tablet
	Composition	Each tablet contains; Progesterone…..100mg
	Diary No. Date of R & I & fee	Dy. No. 10885 dated 05.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0849872 dated 01-03-2019, endorsed on 04.03.2019. <u>Duplicate dossier:</u> Dy. No. 598 dated 06.01.2023
	Pharmacological Group	Pregnen (4) derivatives ATC Code: G03DA04
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	21's, 90's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Endometrin Progesterone 100mg Insert; vaginal USFDA Approved.
	Me-too status	Could not be verified.
	GMP status	Not provided
	Remarks of the Evaluator	i. Provide me-too of the applied product. ii. Provide updated GMP status of M/s Dyson
	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 or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
341.	Name and address of manufacturer/ Applicant	M/s. Marvi Pharmaceuticals, Plot No. 70, Sector 24, Korangi Industrial Area, Karachi. (DML No. 000148) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MISOTEC 50mcg Tablet
	Composition	Each Tablet Contains; Misoprostol…….50mcg
	Diary No. Date of R & I & fee	Dy. No. 13719 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0070447 dated 06-03-2019, endorsed on 07.03.2019
	Pharmacological Group	Prostaglandins ATC Code: A02BB01
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	2x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for applied strength.
	Me-too status	Could not be verified
	GMP status	Not proivded
	Remarks of the Evaluator	i. Reference of finished product specifications is required.

		ii. Evidence of product approval in RRA and also its me-too is required. iii. Latest GMP certificate/ report 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 adopted by the Registration Board in its 275th meeting.**	
342.	Name and address of manufacturer/ Applicant	M/s. Marvi Pharmaceuticals, Plot No. 70, Sector 24, Korangi Industrial Area, Karachi. (DML No. 000148) Sachet (general) Section
	Brand Name + Dosage Form + Strength	Omecarb 40mg+1680mg Sachet
	Composition	Each sachet contains; Omeprazole ……...40mg Sodium bicarbonate….1680mg
	Diary No. Date of R & I & fee	Dy. No. 13717 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0070448 dated 06-03-2019, endorsed on 07.03.2019
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	1x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZEGERID (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved
	Me-too status	Risek Insta Sachet 40mg + 1680mg by M/s Getz Pharma (Reg# 58548)
	GMP status	Not provided
	Remarks of the Evaluator	i. Reference of finished product specifications is required (USP). ii. Latest GMP certificate/ report 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.	
343.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Tablet (general) Section
	Brand Name + Dosage Form + Strength	MEFJEC FORTE 500mg Tablet
	Composition	Each Tablet Contains; Mefenamic acid…… 500mg
	Diary No. Date of R & I & fee	Dy. No. 14994 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734046 dated 06-03-2019, endorsed on 06.03.2019
	Pharmacological Group	Fenamates ATC Code: M01AG01
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mefenamic acid 500 mg film-coated TABLETS - PL 13606/0258 MHRA Approved.
	Me-too status	Ponstan Forte tablet 500mg Reg. No. 006978 M/s Pfizer Laboratories Karachi.
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	Remarks of the Evaluator	i. Clarification is needed as in reference regulatory authorities the applied product is film coated tablet but the applied one is uncoated tablet.

		The deficiency was communicated to the firm vide letter No. 1-1/2020/PEC-DRAP (AD PEC-VII) dated 25.08.2020. The firm vide letter No. OL/DRAP/2020 dated 31.08.2020 submitted reply wherein formulation was revised from uncoated to coated tablet along with fee of Rs. 5000/- vide Slip No. 1921471 endorsed on 02.09.2020. The firm has provided receiving of the fee submitted, copy of deposit slip is not submitted.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
344.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Paradol 37.5mg + 325mg
	Composition	Each tablet contains; Tramadol hydrochloride BP……37.5mg Paracetamol USP…….325mg
	Diary No. Date of R & I & fee	Dy. No. 14990 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734042 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics ATC Code: N02AJ13
	Type of Form	Form-5
	Finished product Specification	**Olive Specifications**
	Pack size & Demanded Price	10's, 20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Tramadol hydrochloride and Paracetamol 37.5 mg/325 mg Film-coated Tablets (tramadol hydrochloride and paracetamol) - PL 30684/0222 MHRA Approved.
	Me-too status	Tonoflex-P Tablet Reg. No. 067163 M/s Sami Pharmaceuticals (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	Remarks of the Evaluator	i. Clarification is needed as in reference regulatory authorities the applied product is film coated tablet but the applied one is uncoated tablet. The deficiency was communicated to the firm vide letter No. 1-1/2020/PEC-DRAP (AD PEC-VII) dated 25.08.2020. The firm vide letter No. OL/DRAP/2020 dated 31.08.2020 submitted reply wherein formulation was revised from uncoated to coated tablet along with fee of Rs. 5000/- vide Slip No. 1921472 endorsed on 02.09.2020. The firm has provided receiving of the fee submitted, copy of deposit slip is not submitted.
	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. **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
345.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Tablet (general) Section
	Brand Name + Dosage Form + Strength	SETAMOL Plus 200mg/30mg/300mg Tablet
	Composition	Each tablet contains; Paracetamol…..…200mg Caffeine…….....…30mg Aspirin…..…….300mg

	Diary No. Date of R & I & fee	Dy. No. 14992 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734044 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	paracetamol, combinations excl. psycholeptics ATC Code: N02BE51
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too status	Could not be verified
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	Remarks of the Evaluator	i. Evidence of approval of applied formulation in reference regulatory authorities/agencies is required which were adopted by the Registration board in its 275th meeting. ii. 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.
	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.**	
346.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Tablet (general) Section
	Brand Name + Dosage Form + Strength	SETAMOL Extra 500mg/60mg/4mg Tablet
	Composition	Each tablet contains; Paracetamol……500mg Pseudoephedrine……..…60mg Chlorpheniramine maleate…..…..….4mg
	Diary No. Date of R & I & fee	Dy. No. 14989 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734041 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	pseudoephedrine, combinations ATC Code: R01BA52
	Type of Form	Form-5
	Finished product Specification	**USP Specifications**
	Pack size & Demanded Price	10's, 20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Panadol CF Tablet Reg. No. 013113 M/s GSK Karachi.
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	Remarks of the Evaluator	i. The finished product specifications are mentioned as USP Specs. Monograph is required. ii. Evidence of approval of applied formulation in reference regulatory authorities/agencies is required 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.	
347.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Tablet (general) Section

	Brand Name + Dosage Form + Strength	Paracine 500mg/10mg Tablet
	Composition	Each film coated tablet contains; Hyoscine butylbromide BP…..10mg Paracetamol USP……500mg
	Diary No. Date of R & I & fee	Dy. No. 14991 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734043 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	Belladonna and derivatives in combination with analgesics, butylscopolamine and analgesics ATC Code: A03DB04
	Type of Form	Form-5
	Finished product Specification	**Olive Specifications**
	Pack size & Demanded Price	10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Buscopan plus film-coated tablets 10 mg/500 mg BPharm Germany Approved.
	Me-too status	Buscopan Plus Tablet Reg. No. 008358.
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	Remarks of the Evaluator	
	Decision: Approved with innovator 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.**	
348.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Tablet (general) Section
	Brand Name + Dosage Form + Strength	GEPROL Forte 650mg/50mg Tablet
	Composition	Each coated tablet contains; Paracetamol……650mg Orphenadrine……50mg
	Diary No. Date of R & I & fee	Dy. No. 14993 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734045 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	orphenadrine, combinations ATC code: M03BC51
	Type of Form	Form-5
	Finished product Specification	**Olive Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be found for applied strength.
	Me-too status	Nuberol Fort Reg. No. 027196 M/s Searle Company Lahore.
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	Remarks of the Evaluator	i. The me-too product uses orphendrine citrate. In applied formulation citrate Is not mentioned. Correction along with full fee is required. ii. 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.	
349.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Capsule (general) Section
	Brand Name + Dosage Form + Strength	GABALIVE 50mg Capsule
	Composition	Each capsule contains; Pregabalin……50mg

	Diary No. Date of R & I & fee	Dy. No. 14995 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734047 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	**Olive Specifications**
	Pack size & Demanded Price	2x7's, 1x10's. 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	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	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.**	
350.	Name and address of manufacturer/ Applicant	M/s. Olive laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat. (DML No. 000524) Capsule (general) Section
	Brand Name + Dosage Form + Strength	GABALIVE 75mg Capsule
	Composition	Each capsule contains; Pregabalin……75mg
	Diary No. Date of R & I & fee	Dy. No. 14996 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0734048 dated 05-03-2019, endorsed on 06.03.2019
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form-5
	Finished product Specification	**Olive Specifications**
	Pack size & Demanded Price	2x7's, 1x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PREGABALIN MANX 75 MG HARD CAPSULES - PL 14251/0145 MHRA Approved.
	Me-too status	Gabica 75mg Cap Reg. No. 048765 M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 12.01.2023. GMP certificate valid till 11.01.2025 is submitted.
	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.**	
351.	Name and address of manufacturer/ Applicant	M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Liquid injectable (psychotropic) Section vide letter No. 1-27/2015-Lic dated 11.04.2018.
	Brand Name + Dosage Form + Strength	Xapax 30mg/??ml Injection
	Composition	Each injection contains; Ephedrine HCl…….30mg
	Diary No. Date of R & I & fee	Dy. No. 16270 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782568 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	Adrenergic and dopaminergic agents ATC Code: C01CA26

	Type of Form	Form-5
	Finished product Specification	**Not mentioned (monograph available in BP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ephedrine Hydrochloride 3mg per ml Solution for Injection (10mL ampoule) MHRA Approved.
	Me-too status	Could not be confirmed
	GMP status	Last inspection conducted on 03.07.2019
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Evidence of me-too product is required. iii. Volume of injection needs to be defined and also whether it will be an ampoule or vial.
	Decision: Deferred for following; • **Submission of details whether product is in ampoule or vial along with its volume.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
352.	Name and address of manufacturer/ Applicant	M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Liquid injection ampoule (general) Section
	Brand Name + Dosage Form + Strength	PTNOL 40mg+0.4mg Injection
	Composition	Each injection contains; Phloroglucnol ……....40mg Trimethylphloroglucinol …..0.4mg
	Diary No. Date of R & I & fee	Dy. No. 16269 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782567 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	Other drugs for functional gastrointestinal disorders. ATC Code: A03AX12
	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	Spasfon Solution for injection in ampoule ANSM France Approved.
	Me-too status	Spasfon Injection Reg. No. 018530 M/s Himont Oharma Lahore.
	GMP status	Last inspection conducted on 03.07.2019
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Reference of finished product specifications is required. iii. Volume of injection needs to be defined and also whether it will be an ampoule or vial.
	Decision: Deferred for following; • **Submission of details whether product is ampoule or vial along with its volume.** • **Reference of finished product specifications.** • **Latest GMP inspection report conducted within last three years.**	
353.	Name and address of manufacturer/ Applicant	M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Ondaset 8mg Tablet
	Composition	Each tablet contains; Ondansetron HCl…….8mg
	Diary No. Date of R & I & fee	Dy. No. 16268 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782566 dated 04-03-2019, endorsed on 05.03.2019

	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	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	Ondansetron 4 mg & 8 mg (Ondansetron Hydrochloride dehydrate) MHRA Approved.
	Me-too status	Zofran Tablets 8 mg Reg. No. 020668 M/s GSK Karachi.
	GMP status	Last inspection conducted on 03.07.2019
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Reference of finished product specifications is required. iii. RRA approved product is film coated, applied product is uncoated. Revision is required. iv. The innovator product's label is of "as HCl", in applied product HCl is included in strength. Correction along with full fee is required.
	Decision: Approved with USP Specifications and following label claim; **Each film coated tablet contains:** **Ondansetron as HCl dihydrate…….8mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 30,000/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
354.	Name and address of manufacturer/ Applicant	M/s. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Tablet (general) Section
	Brand Name + Dosage Form + Strength	Z-X 10mg Tablet
	Composition	Each tablet contains; Escitalopram……10mg
	Diary No. Date of R & I & fee	Dy. No. 16272 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782570 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (available in USP)**
	Pack size & Demanded Price	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 03.07.2019
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. RRA approved product is film coated, applied product is uncoated. Revision is required. iii. Reference of finished product specifications is required. iv. The innovator product's label is of as oxalate, in applied product oxalate is not mentioned. Correction along with full fee is required.
	Decision: Approved with USP Specifications and following label claim; **Each film coated tablet contains:** **Escitalopram as oxalate……10mg**	

	The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 30,000/- for correction/pre-approval change in product label and 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. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Tablet (general) Section
	Brand Name + Dosage Form + Strength	LIVAIR 10mg Tablet
	Composition	Each tablet contains; Montelukast as sodium……..10mg
	Diary No. Date of R & I & fee	Dy. No. 16275 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782573 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	Leukotriene receptor antagonists ATC Code: R03DC03
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (available in USP, BP, JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Montelukast film coated 10mg MHRA Approved
	Me-too status	Montiget 10mg tablet Reg. No. 034838 M/s Getz Pharmaceuticals.
	GMP status	Last inspection conducted on 03.07.2019
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Reference of finished product specifications is required. iii. RRA approved product is film coated, applied product is uncoated. Revision is required along with requisite fee.
	Decision: Approved with USP Specifications and following label claim; **Each film coated tablet contains:** **Montelukast as sodium……..10mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7,500/- for correction/pre-approval change in product label and 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. Liven Pharmaceuticals (Pvt.) Ltd. 49-KM, Lahore Multan Road, Phool Nagar, District kasur. (DML No. 000881) Liquid Ampoule (general) Section
	Brand Name + Dosage Form + Strength	Texa 250mg injection
	Composition	Each injection contains; Tranexamic acid……..250mg
	Diary No. Date of R & I & fee	Dy. No. 16273 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0782571 dated 04-03-2019, endorsed on 05.03.2019
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of Form	Form-5
	Finished product Specification	**Not mentioned (available in USP, BP, JP)**
	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	Not provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report is required. ii. Reference of finished product specifications is required. iii. Evidence of product approval in RRA is required.

		iv. Volume of injection needs to be defined and also whether it will be an ampoule or vial.
	Decision: Deferred for following; • **Submission of details whether product is ampoule or vial along with its volume.** • **Reference of finished product specifications.** • **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.**	
357.	Name and address of Applicant	M/s Leven Medical Care, 8-C Shah Jammal, Lahore.
	Detail of Drug Sale License	M/s Leven Medical Care Address: 8-C, Ground Floor, Street No. 3, Near LGS School, Shah Jamal, District Lahore. Validity: 18.07.2020 Status: License to sell drugs as a distributor (Form No.11)
	Name and address of manufacturer	M/s. Shandong Qidu Pharmaceutical Co. Ltd. No. 17, Hongda Road, Linzi District, Zibo City, Shangdong, China. DML No. Lu 20160064
	Name and address of marketing authorization holder	M/s Sahndong Qidu Pharmaceutical Co. Ltd. No. 17, Hongda Road, Linzi District, Zibo City, Shandong Province P.R. China.
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No. 13122 dated 06.03.19
	Fee including differential fee	Rs.50,000/- Slip No. 0776509 dated 04.03.2019
	Brand Name +Dosage Form + Strength	**Levo carnitine 1g/5ml Injection (IV)**
	Composition	Each 5ml ampoule contains; Levocarnitine …….. 1g
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Amino acids and derivatives ATC Code: A16AA01
	Shelf life	36 months
	Demanded Price	As per SRO.
	Pack size	10x 1's
	International availability	Carnitor 1 g Solution for Injection (5ml Ampoule) MHRA Approved.
	Me-too status	Kefei Injection Reg. No. 059054 M/s RG Pharma (importer)
	Stability studies	Firm has submitted stability studies data summary sheets of 03 batches. The accelerated stability study data is conducted at 40°C ± 2°C/ 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. Batch No. 090201, 090202 & 090203.
	Detail of certificates attached	**Letter of authorization: - (Copy submitted)** M/s Shandong Qidu Pharmaceutical Co. Ltd., No.17, Hongda Road, Linzi District, Zibo city, Shandong China. Authorizes M/s Leven Medical care 8-C Ground Floor Shah Jamal Lahore Dated: 27.06.2018. Validity: Not mentioned. Letter of authorization does not have any sole distribution details. The authorization is only to act as an applicant for submitting registration application for product Levocarnitne Injection 1g/5ml Solution for injection. **Certificate of Pharmaceutical Product:** Not Submitted. **GMP certificate:** Not submitted.
	Remark of the Evaluator [IX]	• Copy of DSL is not clear. Clear Copy of DSL is required.

		• Form 5A is not signed by the applicant. • Intended route of administration needs to be clarified. • The copy of letter of authorization only authorizes M/s Leven Medical Care to act as an agent for submitting registration application. The manufacturer is not authorizing the importer as sole distributor for Pakistan. Proper authorization agreement/ letter is required. • Copy of COPP is required. • Copy of GMP certificate of manufacturer is required. The firm vide letter No. nil, dated 03.03.2023 has submitted the following; • Copy of new license to sell drugs as a distributor **Valid upto** 18.07.2027; **Address:** 8-C, Ground Floor, Street No. 3, Near LGS School, Shah Jamal, District Lahore. **Proprietor:** Adeel ur Rehman s/o Zaka ur Rehman (CNIC 363025641449) H. No. 68 & 69, Jehlum Block, Green Fort-II, Lahore. **Qualified Person:** Hafsa Kiran, d/w/o Muhammad Hussain (CNIC: 3650280740938), Reg. No. 19193-A/18. Chak No. 88-6R, Dak Khana Kot Khadim Ali Shah, Sahiwal. • Properly filled and signed Form-5A is submitted. • Intended route of administration is IV • Copy of letter of Authorization from M/s Shandong Qidu Pharmaceutical Co. Ltd. Wherein the firm has stated that in Pakistan market, Level Medical Care is the authorized and sole distributor of Shandong Qidu Pharmaceutical Co. Ltd • Copy of COPP certificate Certificate No: shandong20223130 Certifying Authority: Shandong Provincial Medical Products Administration, No. 16122, Jingshi road, Jinan City, Shandong Province, P.R. China. Date**:** 19.10.200 The certificate conforms to the format recommended by the WHO. Validity: 18.10.2024 Certificate also confirms that this product is also actually on the market in the exporting country. • Copy of GMP certificate; Certificate No: SD20180804 Manufacturer: Shandong Qidu Pharmaceutical Co. Ltd. No.17, Hongda Road, Linzi District, Zibo City. Issuing Authority: Shandong Food and Drug Adminsitration. Dated: 18.11.2018 Valid till: 17.11.2023
	Decision: Deferred for submission of following; • **Legalized copies of COPP, GMP and Authorization letter.** • **Stability studies of product as per pharmacopoeial specifications because monograph of applied product is available in pharmacopoeia and the manufacturer has manufactured the product as per in-house specifications.**	

Cases of differential Fee

358.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	NILPAIN 15mg Tablets
	Composition	Each tablet contains;

		Meloxicam B.P….15mg
	Diary No. Date of R & I & fee	Dy. No. 25804 dated 13.09.2022. (Duplicate dossier) Dy. No. 91 dated 11.11.10 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Fee paid Rs. 12000/- vide Slip No. 1961620 dated 23-1-2020, endorsed on 29.01.2020.
	Pharmacological Group	Oxicams ATC Code: M01AC06
	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	MELOXICAM 15 MG TABLETS - PL 14251/0098 MHRA Approved.
	Me-too status	Xobix 15mg Tablet Reg. No. 023929 M/s Hilton Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
359.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	NILPAIN 7.5mg Tablets
	Composition	Each tablet contains; Meloxicam B.P….7.5mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 49 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 <u>Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961619 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25779 dated 13.09.2022.
	Pharmacological Group	Oxicams ATC Code: M01AC06
	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	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	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
360.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Acetamol plus Tablets
	Composition	Each tablet contains; Paracetamol USP……...450mg Orphenadrine citrate BP….35mg

	Diary No. Date of R & I & fee	Dy. No. 31963 dated 29.01.2020 (Differential fee) Dy. No. 25789 dated 13.09.2022 (duplicate dossier) Dy. No. 92 dated 11.11.10 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Fee paid Rs. 12000/- vide Slip No. 1961630 dated 23-1-2020, endorsed on 29.01.2020.
	Pharmacological Group	Ethers, chemically close to antihistamines, orphenadrine, combinations. ATC Code: M03BC51
	Type of Form	Form-5
	Finished product Specification	Legacy Specifications.
	Pack size & Demanded Price	10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Norgesic tablets (uncoated) M/s iNova Pharmaceuticals Australia Pvt. Ltd. approved by TGA of Australia
	Me-too status	Nuberol Tablet Reg. No. 020373 M/s Searle Company Ltd Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	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, latest GMP inspection report conducted within last three years before issuance of registration letter	
361.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Metrol 400mg Tablet
	Composition	Each film coated tablet contains; Metronidazole USP…….400mg
	Diary No. Date of R & I & fee	Dy. No. not mentioned dated not mentioned. (Differential fee) Dy. No. 25780 dated 13.09.2022 (duplicate dossier) Dy. No. 95 dated 11.11.10 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Fee paid Rs. 12000/- vide Slip No. 1961616 dated 23-1-2020, endorsed on 29.01.2020.
	Pharmacological Group	Nitroimidazole derivatives ATC Code: P01AB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	20x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Flagyl 400mg Tablets MHRA Approved.
	Me-too status	Flagyl 400mg Tablet Reg. No. 000827 M/s Sanofi Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
362.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Metrol 200mg Tablet
	Composition	Each film coated tablet contains; Metronidazole USP…….200mg
	Diary No. Date of R & I & fee	Initial dossier submission:

		Dy. No. 67 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 <u>For Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961615 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25798 dated 13.09.2022.
	Pharmacological Group	Nitroimidazole derivatives ATC Code: P01AB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	20x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Flagyl 200mg Tablets MHRA Approved.
	Me-too status	Flagyl 200mg Tablet Reg. No. 000910 M/s Sanofi Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
363.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Ebastas 10mg Tablet
	Composition	Each film coated tablet contains; Ebastine BP…….10mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 37 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 <u>For Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961632 dated 23-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25783 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX22
	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	Ebastine Viatris 10mg film-coated tablet ANSM, France Approved.
	Me-too status	Kestine 10mg Tablet Reg. No. 028369 M/s Highnoon Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Specifications of finished product are mentioned as BP. BP monograph is required.
	Decision: Approved with BP Specifications **The firm shall submit latest GMP inspection report/ certificate and 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.**	
364.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Capsule (general) Section.

	Brand Name + Dosage Form + Strength	Legathrocin 500mg Capsule
	Composition	Each capsule contains; Azithromycin as dihydrate USP…….500mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 40 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 For Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961633 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25796 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX22
	Type of Form	Form-5
	Finished product Specification	**Inhouse Specifications**
	Pack size & Demanded Price	6's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for capsule dosage form.
	Me-too status	Bactizith 500mg Capsule Reg. No. 055717 M/s W.Woodwards Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Evidence of approval of product in RRA is required. (capsule 500mg) iii. Monograph of applied product is available n pharmacopoeia, yet inhouse specifications are applied. Clarification or correction 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.	
365.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Talet (general) Section.
	Brand Name + Dosage Form + Strength	Risperide 4mg Tablet
	Composition	Each coated tablet contains; Risperidone BP……4mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 44 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 For Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961640 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25793 dated 13.09.2022.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	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	Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Film-Coated Tablets - PL 29412/0002-7 MHRA Approved.
	Me-too status	Neo-Risp 4mg Tablet Reg No. 085187 M/s Wilshire Laboratories Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.

	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved **The firm shall submit latest GMP inspection report/ certificate before issuance of registration letter.**	
366.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Risperide 1mg Tablet
	Composition	Each coated tablet contains; Risperidone BP……1mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 45 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961637 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25797 dated 13.09.2022.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	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	Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Film-Coated Tablets - PL 29412/0002-7 MHRA Approved.
	Me-too status	Neo-Risp 1mg Tablet Reg No. 085184 M/s Wilshire Laboratories Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
367.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Risperide 2mg Tablet
	Composition	Each coated tablet contains; Risperidone BP……2mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 54 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961638 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25773 dated 13.09.2022.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	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	Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Film-Coated Tablets - PL 29412/0002-7 MHRA Approved.
	Me-too status	Neo-Risp 2mg Tablet Reg No. 085185 M/s Wilshire Laboratories Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
368.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Risperide 3mg Tablet
	Composition	Each coated tablet contains; Risperidone BP……3mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 53 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961639 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25791 dated 13.09.2022.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	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	Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Film-Coated Tablets - PL 29412/0002-7 MHRA Approved.
	Me-too status	Neo-Risp 3mg Tablet Reg No. 085186 M/s Wilshire Laboratories Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
369.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Section.
	Brand Name + Dosage Form + Strength	Rental 200mg Tablet
	Composition	Each tablet contains; Albendazole USP…..200mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 86 dated 11.11.10 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961621 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25794 dated 13.09.2022.
	Pharmacological Group	Benzimidazole derivatives

		ATC Code: P02CA03
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Albendazole 200mg tablet (Film coated) USFDA Approved.
	Me-too status	Zental Tablet (200mg) Reg. No. 006729 M/s GSK Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Details of Ponstel Tablet (Mefenamic acid 250mg) are given. Correct details of Rental 200mg tablet including formula, label claim specifications and pack size along with fee of Rs. 30,000/- is required. iii. The product approved in RRA (USFDA) is film coated, applied product is uncoated. Clarification or correction is required.
	Decision: Deferred for submission of correct details of the product along with fee of Rs. 30,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
370.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Section.
	Brand Name + Dosage Form + Strength	Rental 100mg/5ml Oral Suspension
	Composition	Each 5ml contains; Albendazole USP…..100mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 83 dated 11.11.10 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 <u>Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961622 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25781 dated 13.09.2022.
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA03
	Type of Form	Form-5
	Finished product Specification	**Legacy specifications**
	Pack size & Demanded Price	10ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZENTEL 0.2 g/10 mL oral suspension. ANSM France Approved.
	Me-too status	Zental suspension (100mg) Reg. No. 006730 M/s GSK Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Originally, application of Rentel 100mg/5ml Suspension was submitted, now covering letter of Rental 100mg tablet is submitted. iii. Monograph of applied product is available in pharmacopoeia, yet legacy specs are applied. Clarification or correction is required.
	Decision: Deferred for following; • **Clarification regarding change from suspension to tablet** • **Revision of specifications along with fee of Rs. 7500/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 if required.** • **Latest GMP inspection report conducted within last three years.**	

371.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Toradol 50mg Tablet
	Composition	Each tablet contains; Tramadol Hydrochloride BP……50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 49 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961641 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25803 dated 13.09.2022.
	Pharmacological Group	Other opioids ATC Code: N02AX02
	Type of Form	Form-5
	Finished product Specification	Legacy specifications
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Tramadol Hydrochloride 50mg Oral Tablet (film Coated) USFDA Approved.
	Me-too status	Damor 50mg Tablet Reg. No. 073707 M/s Opal Labs Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia, yet legacy specs are applied. Clarification or correction is required. iii. The product approved in RRA is film coated tablet, applied product is uncoated. Clarification or correction along with full fee is required.
	Decision: Approved with USP Specifications and following label claim; **Each film coated tablet contains:** **Tramadol Hydrochloride ……50mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7,500/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
372.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	Toradol 100mg Tablet
	Composition	Each tablet contains; Tramadol Hydrochloride BP……100mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 50 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961642 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25786 dated 13.09.2022.
	Pharmacological Group	Other opioids ATC Code: N02AX02
	Type of Form	Form-5
	Finished product Specification	Legacy specifications

	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Oldaram 100mg Prolonged-Release Tablets (tramadol hydrochloride) - PL 14894/0339 MHRA Approved.
	Me-too status	Tramal SR 100mg Tablet Reg. No. 023317 M/s Searle Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. The product approved in RRA and me-too is SR tablet, applied product is uncoated. Clarification or correction along with full fee is required. iii. Monograph of applied product is available in pharmacopoeia, yet legacy specs are applied. Clarification or correction is required.
	Decision: Approved with USP Specifications and following label claim; **Each sustained release tablet contains:** **Tramadol Hydrochloride BP……100mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 30,000/- for correction/pre-approval change in product label and 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 Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Capsule (General) Section.
	Brand Name + Dosage Form + Strength	Trancid 250mg Capsule
	Composition	Each capsule contains; Tranexamic acid BP……250mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 52 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961643 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 257805 dated 13.09.2022.
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of Form	Form-5
	Finished product Specification	Legacy specifications
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Hexatron capsule 250mg PDMA Japan Approved.
	Me-too status	Haemic Capsule 250mg Reg. No. 039014 M/s Genix Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia (JP), yet legacy specs are applied. Clarification or correction is required.
	Decision: Approved with JP Specifications **The firm shall submit latest GMP inspection report/ certificate and 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.**	
374.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632)

		Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Trancid 500mg Capsule
	Composition	Each capsule contains; Tranexamic acid BP……500mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 51 dated 23.02.11 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961644 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25776 dated 13.09.2022.
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of Form	Form-5
	Finished product Specification	Legacy specifications
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for capsule dosage form.
	Me-too status	Haemic Capsule 500mg Reg. No. 039016 M/s Genix Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia (JP), yet legacy specs are applied. Clarification or correction is required. iii. 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 conducted within last three years.**	
375.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Fexor 60mg tablet
	Composition	Each tablet contains; Fexofenadine HCl……60mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 47 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961603 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25790 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX26
	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	ALLEGRA 60mg Film-coated Tablets USFDA Approved.
	Me-too status	Fexet Tablet 60mg Reg. No. 029434

		M/s Getz Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i.Latest GMP certificate/ inspection report is required. ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision: Approved with following label claim; **Each film coated tablet contains:** **Fexofenadine HCl……60mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7500/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
376.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Fexor 120mg tablet
	Composition	Each tablet contains; Fexofenadine HCl……120mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 72 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 <u>Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961603 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25772 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX26
	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	Fexofenadine Hydrochloride 120 mg and 180 mg Film-coated tablets PL 21880/0259-0260; UK/H/7053/002-003/DC MHRA Approved.
	Me-too status	Fexet Tablet 120mg Reg. No. 029435 M/s Getz Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision: Approved with following label claim; **Each film coated tablet contains:** **Fexofenadine HCl……120mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7500/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
377.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.

	Brand Name + Dosage Form + Strength	Fexor 180mg tablet
	Composition	Each tablet contains; Fexofenadine HCl……180mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 46 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961605 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25778 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX26
	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	Fexofenadine Hydrochloride 120 mg and 180 mg Film-coated tablets PL 21880/0259-0260; UK/H/7053/002-003/DC MHRA Approved.
	Me-too status	Fexet Tablet 180mg Reg. No. 029436 M/s Getz Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision: Approved with following label claim; **Each film coated tablet contains:** **Fexofenadine HCl……180mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7500/- for correction/pre-approval change in product label and 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 Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Fexor Plus 60mg/120mg tablet
	Composition	Each tablet contains; Fexofenadine HCl USP……60mg Pseudoephedrine USP…..120mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 75 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.11.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961606 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25792 dated 13.09.2022.
	Pharmacological Group	pseudoephedrine, combinations R01BA52
	Type of Form	Form-5
	Finished product Specification	In-house specifications

	Pack size & Demanded Price	10's. 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	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Approval of product in Reference Regulatory Authorities is required.(product approved in RRA is Sustained release)
	Decision: Approved with USP specifications as per following label claim; **Each sustained release tablet contains:** **Fexofenadine HCl USP……60mg** **Pseudoephedrine USP…..120mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 30,000/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
379.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	KT-Zol 200mg tablet
	Composition	Each tablet contains; Ketoconazole……200mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 34 dated 23.02.2011 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 <u>Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961631 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25787 dated 13.09.2022.
	Pharmacological Group	CORTICOSTEROIDS FOR SYSTEMIC USE, Anticorticosteroids ATC Code: H02CA03
	Type of Form	Form-5
	Finished product Specification	Legacy Specifications
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketoconazole HRA 200 mg tablets MHRA Approved.
	Me-too status	KZ 200mg Tablet Reg. No. 092348 M/s Seraph Pharmaceutical, Plot No.210, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia, yet legacy specs are applied. Clarification or correction is required.
	Decision: Approved with USP Specifications.	

	The firm shall submit latest GMP inspection report/ certificate 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, before issuance of registration letter.	
380.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Nilclot 75mg Tablet
	Composition	Each tablet contains; Clopidogrel (as bisulfate) USP ….75mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 58 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961618 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25787 dated 13.09.2022.
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin ATC Code: B01AC04
	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	CLOPIDOGREL 75 MG FILM-COATED TABLETS - PL 36687/0275 MHRA Approved.
	Me-too status	Abiclot Tablet 75mg Reg. No. 033843 M/s Martin Dow Ltd. Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. The applied product is uncoated, whereas product approved in RRA is film coated. Justification or correction along with requisite fee (Rs. 7500/-) is required.
	Decision: Approved with following label claim; **Each film coated tablet contains:** **Clopidogrel (as bisulfate) USP ….75mg** **The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7500/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
381.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Oral Liquid (general) Section.
	Brand Name + Dosage Form + Strength	Rolac 3.35mg/5ml Syrup
	Composition	Each 5ml contains; Lactulose USP ….3.35g
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 69 dated 11.11.2010 RnI verified. Initial fee Rs. 15000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. **Fee paid Rs. 5000**/- vide Slip No. 1961645 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25785 dated 13.09.2022.

	Pharmacological Group	Osmotically acting laxatives ATC Code: A06AD11
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	120ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LACTULOSE 3.35 G/5 ML ORAL SOLUTION, LACTULOSE SOLUTION MHRA Approved.
	Me-too status	Helilac syrup 3.35mg/5ml Reg. No. 025818 M/s Helicon Pharmacutek Faisalabad
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Source of lactulose is required to be defined.
	Decision: Deferred for following; • **Source of Lactulose along with stability studies data, GMP certificate of supplier and differential fee in case of import.** • **Latest GMP inspection report conducted within last three years.**	
382.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Asthafen 1mg Tablet
	Composition	Each tablet contains; Ketotifen (as hydrogen fumarate) BP…….1mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 59 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 <u>Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961602 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25788 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX17
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZADITEN TABLETS 1MG MHRA Approved
	Me-too status	Asthotifen tablet Reg. No. 010262 M/s Zafa Pharmaceutical Lab (Pvt.) Ltd. Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
383.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Asthafen 1mg/5ml Syrup
	Composition	Each 5ml contains; Ketotifen (as hydrogen fumarate) BP…….1mg

	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 57 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961601 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25795 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX17
	Type of Form	Form-5
	Finished product Specification	**Rock Specifications**
	Pack size & Demanded Price	60ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too status	Zatofen Syrup Reg. No. 005804 M/s Novartis Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Rock Specifications are applied. Correction along with submission of requisite fee is required. iii. Evidence of applied product approval in RRA 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.** • **Revision of Specification along with fee of Rs. 7,500/- as per No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Latest GMP inspection report conducted within last three years.**	
384.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Loroc 10mg Tablet
	Composition	Each tablet contains; Loratadine USP…….10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 65 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961612 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25775 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	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	LORATADINE 10MG TABLETS MHRA Approved.
	Me-too status	Zordin Tablet 10mg Reg. No. 024806 M/s Global Pharma Islamabad.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.

	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
385.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Section.
	Brand Name + Dosage Form + Strength	Loroc 5mg/5ml Syrup
	Composition	Each 5ml contains; Loratadine USP…….5mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 61 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961613 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25800 dated 13.09.2022.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	60ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	LORATADINE 5 MG/5ML ORAL SOLUTION - PL 20395/0330 MHRA Approved.
	Me-too status	Softin Syrup Reg. No. 024780 M/s Werrick pharma Islamabad.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia, applied specs are Legacy specs. Clarification or correction along with requisite fee is required.
	Decision: Approved with USP Specifications. **The firm shall submit latest GMP inspection report/ certificate 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, before issuance of registration letter.**	
386.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Montekast 10mg Tablet
	Composition	Each tablet contains; Montelukast sodium eq to montelukast..……10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 52 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961617 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25801 dated 13.09.2022.
	Pharmacological Group	Leukotriene receptor antagonist

		ATC Code: R03DC03
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	2x7's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MONTELUKAST 10 MG FILM-COATED TABLETS - PL 49445/0040 MHRA Approved
	Me-too status	Singulair 10mg Tablet Reg. No. 025259 M/s OBS Healthcare Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia, applied specs are Legacy specs. Clarification or correction along with requisite fee is required. iii. Applied product is uncoated. RRA(MHRA) approved is film coated. Clarification or correction is required.
	Decision: Approved with USP Specifications and following label claim; Each film coated tablet contains: Montelukast sodium eq. to Montelukast ...……. 10mg The firm shall submit latest GMP inspection report/ certificate and fee of Rs. 7500/- for correction/pre-approval change in product label and specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
387.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Legrex 2mg Tablet
	Composition	Each tablet contains; Tizanidine HCl eq to Tizanidine..…….2mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 53 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 <u>Differential fee:</u> Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961607 dated 27-1-2020, endorsed on 29.01.2020. <u>Duplicate Dossier:</u> Dy. No. 25774 dated 13.09.2022.
	Pharmacological Group	Other centrally acting agents ATC Code: M03BX02
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	20's. 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	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia, applied specs are Legacy specs. Clarification or correction along with requisite fee is required.

	Decision: Approved with USP Specifications **The firm shall submit latest GMP inspection report/ certificate 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, before issuance of registration letter.**	
388.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Masofenac 50mg/200mcg Tablet
	Composition	Each enteric coated tablet contains; Diclofenac sodium …..50mg Misoprostol……200mcg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 70 dated 11.11.2010 RnI verified. Initial fee Rs. 8000/- paid on 27.10.2010, endorsed on 11.10.2010 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961614 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25802 dated 13.09.2022.
	Pharmacological Group	Prostaglandins ATC code: A02BB01 Acetic acid derivatives and related substances ATC code: M01AB05
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Diclofenac sodium and misoprostol 50 mg/200 micrograms and 75 mg/200 micrograms modified release tablets (diclofenac sodium and misoprostol) - UK/H/5263/001-2/DC;PL 33100/0008-9 MHRA Approved.
	Me-too status	Rotec 50mg/200mcg tablet Reg. No. 053327 M/s the Searle Company Ltd. Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia, applied specs are Legacy specs. Clarification or correction along with requisite fee is required.
	Decision: Deferred for following: • **Revision of label claim for bilayer tablet as per innovator product.** • **Evidence of availability of bilayer tablet compression machine.**	
389.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Legofen-P 75mg Tablet
	Composition	Each film coated tablet contains; Diclofenac potassium USP …..75mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 27 dated 23.02.2011 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961634 dated 27-1-2020, endorsed on 29.01.2020.

		Duplicate Dossier: Dy. No. 25802 dated 13.09.2022.
	Pharmacological Group	Acetic acid derivatives and related substances ATC code: M01AB05
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	10's, 20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for applied strength.
	Me-too status	Caflam 50mg Tablets Reg. No. 021528 M/s Novartis Pharma Karachi.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Evidence of product approval in RRA is required. iii. Monograph of applied product is available in pharmacopoeia, applied specs are Legacy specs. Clarification or correction along with requisite fee is required.
	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.**	
390.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lumethar 20mg/120mg Tablet
	Composition	Each film coated tablet contains; Artemether……..20mg Lumefantrine……120mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 47 dated 23.02.2011 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961635 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25782 dated 13.09.2022.
	Pharmacological Group	Artemisinin and derivatives, combinations ATC Code: P01BF01
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	10's, 16's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	WHO Approved formulation
	Me-too status	Artemet-L tablet Reg. No. 050862 M/s Pulse Pharmaceuticals Lahore.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Monograph of applied product is available in pharmacopoeia (Ph. Int), applied specs are Legacy specs. Clarification or correction along with requisite fee is required.
	Decision: Approved with International Pharmacopoeia specifications. **The firm shall submit latest GMP inspection report/ certificate 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, before issuance of registration letter.**	

391.	Name and address of manufacturer/ Applicant	M/s Legacy Pharmaceutical (Pvt.) Ltd. 111-A, Industrial Estate, Hayatabad, Peshawar (DML No. 000632) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	Lumethar DS 40mg/240mg Tablet
	Composition	Each film coated tablet contains; Artemether……..20mg Lumefantrine……120mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 46 dated 23.02.2011 RnI verified. Initial fee Rs. 8000/- paid on 21.01.2011, endorsed on 22.02.2011 Differential fee: Dy. No. not mentioned dated not mentioned. Fee paid Rs. 12000/- vide Slip No. 1961636 dated 27-1-2020, endorsed on 29.01.2020. Duplicate Dossier: Dy. No. 25784 dated 13.09.2022.
	Pharmacological Group	Artemisinin and derivatives, combinations ATC Code: P01BF01
	Type of Form	Form-5
	Finished product Specification	**Legacy Specifications**
	Pack size & Demanded Price	8's, 10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	WHO approved formulation
	Me-too status	Artemetf Reg. No. 056334 M/s Panacea Pharma Rawat.
	GMP status	Inspection conducted on 18.07.2019. Its older than 3 years old.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Section approval letter is required. iii. Monograph of applied product is available in pharmacopoeia (Ph. Int), applied specs are Legacy specs. Clarification or correction along with requisite fee is required.
	Decision: Approved with International Pharmacopoeia specifications. The firm shall submit latest GMP inspection report/ certificate 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, before issuance of registration letter.	
392.	Name and address of manufacturer/ Applicant	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-KM, Multan Road, Lahore. (DML No. 000228) Section. Tablet (General) Section
	Brand Name + Dosage Form + Strength	NERVAX 30mg Tablet
	Composition	Each tablet contains; Duloxetine as Hydrochloride……30mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 504 dated 21.03.2012 RnI verified. Initial fee Rs. 8000/- paid on 23.02.2012, endorsed on 21.03.2012 Differential fee: Dy. No. 411 dated 6.02.2020. Fee paid Rs. 12000/- vide Slip No. 2003059 dated 30-01-2020, endorsed on 30.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC code: N06AX21
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	20's, 10's. As per SRO.

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for tablet dosage form
	Me-too status	Could not be verified for applied dosage form.
	GMP status	Last GMP inspection conducted on 04.02.2020.
	Remarks of the Evaluator	i. Evidence of RRA approval of applied product (in tablet dosage form) is required. ii. Evidence of me-too product (tablet dosage form) is required. iii. Specifications of finished product are required to be defined. iv. Latest GMP inspection report/certificate is required, provided one is older than 3 years.
	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.** • **The firm shall submit latest GMP inspection report conducted within last three years**	
393.	Name and address of manufacturer/ Applicant	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-KM, Multan Road, Lahore. (DML No. 000228) Tablet (psychotropic) Section.
	Brand Name + Dosage Form + Strength	CLONAM 10mg Tablets
	Composition	Each tablet contains; Clobazam……10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 1229 dated 16.04.2012 RnI verified. Initial fee Rs. 8000/- paid on 09.04.2012, endorsed on 16.04.2012 Differential fee: Dy. No. 408 dated 6.02.2020. Fee paid Rs. 12000/- vide Slip No. 2003062 dated 30-01-2020, endorsed on 30.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Benzodiazepine derivatives ATC Code: N05BA09
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	100's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Clobazam Accord 10mg Tablets MHRA Approved.
	Me-too status	Frisium Tablets 10mg Reg. No. 002694 M/s Sanofi Aventis Pakistan Ltd. Karachi.
	GMP status	Last GMP inspection conducted on 04.02.2020.
	Remarks of the Evaluator	i. Specifications of finished product are required to be defined. (Monograph available in BP) ii. Latest GMP inspection report/certificate is required. Provided one is older than 3 years.
	Decision: Approved with BP Specifications. **The firm shall submit latest GMP inspection report conducted within last three years 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, before issuance of registration letter.**	
394.	Name and address of manufacturer/ Applicant	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-KM, Multan Road, Lahore. (DML No. 000228) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Leucocin 15mg Tablets
	Composition	Each tablet contains; Leucovorin (folinic acid) as calcium……15mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 1234 dated 16.04.2012 RnI verified.

		Initial fee Rs. 8000/- paid on 28.03.2012, endorsed on 16.04.2012 Differential fee: Dy. No. 162 dated 7.02.2020. Fee paid Rs. 12000/- vide Slip No. 2003060 dated 30-01-2020, endorsed on 30.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Detoxifying agents for antineoplastic treatment calcium folinate ATC Code: V03AF03
	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	Refolinon 15mg tablets MHRA Approved.
	Me-too status	Could not be verified.
	GMP status	Last GMP inspection conducted on 04.02.2020.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate is required. Provided one is older than 3 years. ii. Evidence of me-too product 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 or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
395.	Name and address of manufacturer/ Applicant	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-KM, Multan Road, Lahore. (DML No. 000228) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Leucocin 25mg Tablets
	Composition	Each tablet contains; Leucovorin (folinic acid) as calcium……25mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 1234 dated 16.04.2012 RnI verified. Initial fee Rs. 8000/- paid on 28.03.2012, endorsed on 16.04.2012 Differential fee: Dy. No. 163 dated 7.02.2020. Fee paid Rs. 12000/- vide Slip No. 2003061 dated 30-01-2020, endorsed on 30.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Detoxifying agents for antineoplastic treatment calcium folinate ATC Code: V03AF03
	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	LEUCOVORIN CALCIUM EQ 25MG BASE Oral Tablet USFDA Approved.
	Me-too status	Could not be verified
	GMP status	Last GMP inspection conducted on 04.02.2020.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate is required. Provided one is older than 3 years. ii. Evidence of me-too product 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 or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
396.	Name and address of manufacturer/ Applicant	M/s Tagma Pharm (Pvt.) Ltd. 12.5KM Raiwind Road Lahore. (DML No. 000414) Tablet (general) Section.

	Brand Name + Dosage Form + Strength	KENAVIR 0.5mg Tablets
	Composition	Each tablet contains; Entecavir ……0.5mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 690 dated 27.12.2010 RnI verified. Initial fee Rs. 8000/- paid on 24.12.2010, endorsed on 16.04.2012 Differential fee: Dy. No. 480 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1953746 dated 27-01-2020, endorsed on 30.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Nucleoside and nucleotide reverse transcriptase inhibitors ATC Code: J05AF10
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Entecavir Kent 0.5 and 1 mg film-coated tablets (Entecavir monohydrate) - PL 08215/0104-5; UK/H/6427/001-2/DC MHRA Approved
	Me-too status	Previr 0.5mg Tablet Reg. No. 056601 M/s Navegal Laboratories Peshawar.
	GMP status	Inspection conducted on 17.06.2019
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate is required. ii. The innovator product is film coated and uses monohydrate. Revision as per innovator product along with submission of full fee is required.
	Decision: Approved with innovator specifications and following label claim; **Each film coated tablet contains:** **Entecavir as monhydrate ……0.5mg** **The firm shall submit latest GMP inspection report conducted within last three years and fee of Rs. 30,000/- for correction/pre-approval change in product label and 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 Tagma Pharm (Pvt.) Ltd. 12.5KM Raiwind Road Lahore. (DML No. 000414) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	KENAVIR 1mg Tablets
	Composition	Each tablet contains; Entecavir ……1mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 691 dated 27.12.2010 RnI verified. Initial fee Rs. 8000/- paid on 24.12.2010, endorsed on 16.04.2012 Differential fee: Dy. No. 479 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1953745 dated 27-01-2020, endorsed on 30.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Nucleoside and nucleotide reverse transcriptase inhibitors ATC Code: J05AF10
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications**
	Pack size & Demanded Price	30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Entecavir Kent 0.5 and 1 mg film-coated tablets (Entecavir monohydrate) - PL 08215/0104-5; UK/H/6427/001-2/DC MHRA Approved
	Me-too status	Previr 1mg Tablet Reg. No. 056602

		M/s Navegal Laboratories Peshawar.
	GMP status	Inspection conducted on 17.06.2019
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate is required. ii. The innovator product is film coated and uses monohydrate. Revision as per innovator product along with submission of full fee is required.
	Decision: Approved with innovator specifications and following label claim; **Each film coated tablet contains:** **Entecavir as monhydrate ……1mg** **The firm shall submit latest GMP inspection report conducted within last three years and fee of Rs. 30,000/- for correction/pre-approval change in product label and 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 Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 25mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……25mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 250 dated 27.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927655 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	**Form-5D**
	Finished product Specification	**Scotmann Specs.**
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
399.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 50mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 257 dated 27.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927654 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier:

		Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	**Form-5D**
	Finished product Specification	**Scotmann Specs.**
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
400.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 12.5mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……12.5mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 249 dated 25.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. <u>Differential fee:</u> Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 2000501 dated 31-01-2020, endorsed on 31.01.2020. <u>Duplicate Dossier:</u> Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	Form-5D
	Finished product Specification	Scotmann Specs.
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
401.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	MILNA 100mg Tablets
	Composition	Each film coated tablet contains; Milnacipran HCl……100mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 252 dated 25.07.2009 RnI verified. Initial fee Rs. 15000/- paid on 13.07.2009, endorsed on 25.07.2009. <u>Differential fee:</u>

		Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 2000502 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antidepressants ATC Code: N06AX17
	Type of Form	Form-5D
	Finished product Specification	Scotmann Specs.
	Pack size & Demanded Price	14's, 28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Savella Milnacipran hydrochlorie 12.5mg, 25mg, 50mg, 100mg Tablet Film Coated immediate release tablets. USFDA Approved.
	Me-too status	Could not be found
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision: Deferred for submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
402.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	NOBU 10mg Tablet
	Composition	Each tablet contains; Nebivolol HCl……10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 9321 dated 07.10.2010 RnI verified. Initial fee Rs. 15000/- paid on 21.09.2010, endorsed on 07.10.2010. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 5000/- vide Slip No. 1927666 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Beta blocking agents, selective ATC code: C07AB12
	Type of Form	Form-5D
	Finished product Specification	Scotmann Specs.
	Pack size & Demanded Price	10's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	NEBIVOLOL 10MG TABLETS MHRA Approved.
	Me-too status	Nebil Tablet 10mg Reg. No. 061346 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. The innovator product contains nebivolol 10mg as HCl. Applied label is of Nebivolol HCl 10mg. Justification or correction along with full fee is required. ii. The fee paid is total Rs. 20,000/- that is of Form 5. Application is submitted on Form-5D. Me-too of the applied product is also available. Justification or revision of application Form from 5D to 5 is required.
	Decision: Approved with innovator's specifications as per following label claim: **Nebivolol as hydrochloride …. 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.	
403.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	NOBU 20mg Tablet
	Composition	Each tablet contains; Nebivolol HCl……20mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 9320 dated 07.10.2010 RnI verified. Initial fee Rs. 15000/- paid on 21.09.2010, endorsed on 07.10.2010. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927665 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Beta blocking agents, selective ATC code: C07AB12
	Type of Form	**Form-5D**
	Finished product Specification	**Scotmann Specs.**
	Pack size & Demanded Price	10's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Bystolic Nebivolol HCl eq 20mg Base Tablet oral USFDA Approved.
	Me-too status	Could not be verified
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. The innovator product contains nebivolol 10mg as HCl. Applied label is of Nebivolol HCl 10mg. Justification or correction along with full fee is required. ii. Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required.
	Decision: Deferred for following; • **Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.** • **Correction of label as per innovator product along with submission of fee of Rs 30,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
404.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	ATMOS Flash 20mg Tablets
	Composition	Each tablet contains; Ebastine……20mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 6974 dated 22.07.2010 RnI verified. Initial fee Rs. 8000/- paid on 16.07.2010, endorsed on 22.07.2010. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1927668 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX22

	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	ALASTINA 20mg CIMA, Spain Approved.
	Me-too status	Kestine 20 mg tablet Reg. No. 025432 M/s Highnoon Laboratories Ltd Lahore.
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. No reference of finished product specifications is given. The monograph of applied product is available in JP. Revision of specs along with fee of Rs.7500/- is required. ii. The product approved in RRA is a film coated tablet, whereas applied product is uncoated. Clarification or correction is required. iii. Similar formulation is registered vide Reg No. 060262 (Atmos tab 20mg) Justification of applying with different name is required.
	Decision: Deferred for clarification for applying already registered formulation with different name.	
405.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	ATMOS Flash 10mg Tablets
	Composition	Each tablet contains; Ebastine……10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 6983 dated 22.07.2010 RnI verified. Initial fee Rs. 8000/- paid on 16.07.2010, endorsed on 22.07.2010. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1927670 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX22
	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	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	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. No reference of finished product specifications is given. The monograph of applied product is available in JP. Revision of specs along with fee of Rs.7500/- is required. ii. The product approved in RRA is a film coated tablet, whereas applied product is uncoated. Clarification or correction is required. iii. Similar formulation is registered vide Reg No. 056116 (Atmos tab 10mg) Justification of applying with different name is required.
	Decision: Deferred for clarification for applying already registered formulation with different name.	

406.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	JADE Flash 10mg Tablets
	Composition	Each tablet contains; Loratadine……10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 6981 dated 22.07.2010 RnI verified. Initial fee Rs. 8000/- paid on 16.07.2010, endorsed on 22.07.2010. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1927667 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	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	LORATADINE 10MG TABLETS PL 00142/0479 MHRA Approved.
	Me-too status	Jade Tablet Reg. No. 028265 M/s Scotmann Pharmaceuticals
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. Applied formulation is already registered vide Reg. No. 028265 (jade 10mg tablet). Clarification is required why again is applied. ii. No reference of finished product specifications is given. The monograph of applied product is available in JP. Revision of specs along with fee of Rs.7500/- is required.
	Decision: Deferred for clarification for applying already registered formulation with different name.	
407.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Section.
	Brand Name + Dosage Form + Strength	MOZART INSTA 50mg Injection (IM)
	Composition	Each Vial contains; Risperidone microsphere equivalent to risperidone..50mg Composition of diluent; Polysorbate 20…..0.1mg……..0.1mg Sodium carboxymethyl cellulose…….1.5mg Disodium hydrogen phosphate dehydrate…..1mg Citric acid anhydrous ……..3mg Sodium hydroxide…..For pH adjustment Water for injection…..QS
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 161 dated 20.05.2009 RnI verified. Initial fee Rs. 15000/- paid on 20.04.2009, endorsed on 20.05.2009. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927652 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.

	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	Type of Form	Form-5D
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	RISPERDAL CONSTA, 25mg, 37.5mg, 50mg, 12.5mg/vial, intramuscular injection USFDA Approved.
	Me-too status	Not available
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required. ii. Volume of diluent is not provided. Will it be in prefilled syringes? Is section of prefilled syringes approved? (Evidence of manufacturing facility to produce product as innovator is required.) iii. Will microspheres be made in house or will be purchased? What will be the source of microspheres?
	Decision: Deferred for following; • **Evidence of availability of required manufacturing facility for applied formulation, with reference to innovator product.** • **Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**	
408.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Section.
	Brand Name + Dosage Form + Strength	MOZART INSTA 25mg Injection (IM)
	Composition	Each Vial contains; Risperidone microsphere equivalent to risperidone..25mg Composition of diluent; Polysorbate 20…..0.1mg……..0.1mg Sodium carboxymethyl cellulose…….1.5mg Disodium hydrogen phosphate dehydrate…..1mg Citric acid anhydrous ……..3mg Sodium hydroxide…..For pH adjustment Water for injection…..QS
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 160 dated 20.05.2009 RnI verified. Initial fee Rs. 15000/- paid on 20.04.2009, endorsed on 20.05.2009. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927657 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	Type of Form	Form-5D
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	RISPERDAL CONSTA, 25mg, 37.5mg, 50mg, 12.5mg/vial, intramuscular injection USFDA Approved.
	Me-too status	Not available
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.

	Remarks of the Evaluator	i. Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required. ii. Volume of diluent is not provided. Will it be in prefilled syringes? Is section of prefilled syringes approved? (Evidence of manufacturing facility to produce product as innovator is required.) iii. Will microspheres be made in house or will be purchased? What will be the source of microspheres?
	Decision: Deferred for following; • **Evidence of availability of required manufacturing facility for applied formulation, with reference to innovator product.** • **Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**	
409.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Section.
	Brand Name + Dosage Form + Strength	MOZART INSTA 37.5mg Injection (IM)
	Composition	Each Vial contains; Risperidone microsphere equivalent to risperidone..37.5mg Composition of diluent; Polysorbate 20…..0.1mg……..0.1mg Sodium carboxymethyl cellulose…….1.5mg Disodium hydrogen phosphate dehydrate…..1mg Citric acid anhydrous ……..3mg Sodium hydroxide…..For pH adjustment Water for injection…..QS
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 162 dated 20.05.2009 RnI verified. Initial fee Rs. 15000/- paid on 20.04.2009, endorsed on 20.05.2009. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 35000/- vide Slip No. 1927656 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	Type of Form	Form-5D
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	RISPERDAL CONSTA, 25mg, 37.5mg, 50mg, 12.5mg/vial, intramuscular injection USFDA Approved.
	Me-too status	Not available
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. Drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting is required. ii. Volume of diluent is not provided. Will it be in prefilled syringes? Is section of prefilled syringes approved? (Evidence of manufacturing facility to produce product as innovator is required.) iii. Will microspheres be made in house or will be purchased? What will be the source of microspheres?
	Decision: Deferred for following; • **Evidence of availability of required manufacturing facility for applied formulation, with reference to innovator product.**	

	• **Submission of stability study data as per the guidelines approved in 293rd meeting of Registration Board.**	
410.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	NERVOLOGIC 500mcg Tablets
	Composition	Each tablet contains; Mecobalamin……500mcg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 1771 dated 20.01.2011 RnI verified. Initial fee Rs. 8000/- paid on 19.01.2011, endorsed on 20.01.2011. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1927664 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	10's, 20's, 30's 100's As per SRO.
	Approval status of product in Reference Regulatory Authorities	Neumethecol 500mcg tablet by Hisui pharma (PMDA Japan approved)
	Me-too status	Acobmin 500mcg sugar coated tablet of M/s Cunningham Pharmaceuticals, Lahore. Registration No. 101801
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. Product approved in RRA and me-too is sugar coated. Applied product is uncoated tablet. Justification or correction along with fee is required. ii. Reference of Specifications of finished product is not mentioned. Monograph of applied product is available in pharmacopoeia.
	Decision: Approved with JP specifications and following label claim; **Each sugar coated tablet contains:** **Mecobalamin……500mcg** **The firm shall submit latest GMP inspection report conducted within last three years and fee of Rs. 30,000/- for correction/pre-approval change in product label and 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 Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Liquid Ampoule (general) Section.
	Brand Name + Dosage Form + Strength	NERVOLOGIC 500mcg/??ml Injection
	Composition	Each ml Ampoule contains; Mecobalamin……500mcg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 1770 dated 20.01.2011 RnI verified. Initial fee Rs. 8000/- paid on 19.01.2011, endorsed on 20.01.2011. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1927663 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5

	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	1's, 10's As per SRO.
	Approval status of product in Reference Regulatory Authorities	METHYCOBAL 500µg injection PDMA Japan Approved.
	Me-too status	Reli-cobal Injection 500mcg Reg. No. 083440 M/s Reliance Pharma
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. Volume of ampoule is not mentioned. It is required.
	Decision: Deferred for clarification of applied fill volume of the ampoule.	
412.	Name and address of manufacturer/ Applicant	M/s IMCO Pharmaceutical Laboratories (Pvt.) Ltd. 73-Industrial Estate, Hayatabad, Peshawar. (DML No. 000317) Section.
	Brand Name + Dosage Form + Strength	B-Tyle 4mg sachet
	Composition	Each sachet contains; Montelukast…..4mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 461 dated 14.03.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.03.2011, endorsed on 14.03.2011 <u>Differential fee:</u> Dy. No. 31385 dated 23.01.2020. Fee paid Rs. 12000/- vide Slip No. 0816673 dated 20-01-2020, endorsed on 23.01.2020. <u>Duplicate Dossier:</u> Dy. No. 27117 dated 26.09.2022
	Pharmacological Group	Leukotriene receptor antagonists ATC Code: R03DC03
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MONTELUKAST 4 MG GRANULES - PL 36687/0448 MHRA Approved
	Me-too status	Singulair 4mg granules Reg. No. 031377 M/s OBS Healthcare (Pvt.) Ltd. Karachi.
	GMP status	Inspection conducted on 07.04.2014.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Section approval letter and copy of DML along with renewal status is required. iii. Product approved in RRA is as sodium salt and granules. Correction along with full fee is required. iv. Specifications of finished product are not mentioned. Monograph of applied product is available in pharmacopoeia (USP).
	Decision: Deferred for following; • **Latest GMP inspection report conducted within last three years** • **Evidence of approval of required manufacturing facility i.e., "Sachet (general) section.** • **Revision of label claim for complete salt form of drug substance as per innovator product along with submission of fee of Rs. 30,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Submission of reference of specifications of finished product** • **Confirmation of validity status of DML.**	
413.	Name and address of manufacturer/ Applicant	M/s IMCO Pharmaceutical Laboratories (Pvt.) Ltd. 73-Industrial Estate, Hayatabad, Peshawar. (DML No. 000317) Section.
	Brand Name + Dosage Form + Strength	S-NIL Cream

	Composition	Each 50g contains; Lindane …..0.50g Ceto Sterial Alcohol…..24.75g Liquid propylin….24.75g
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 259 dated 23.06.2011 RnI verified. Initial fee Rs. 8000/- paid on 23.06.2011, endorsed on 23.06.2011 Differential fee: Dy. No. 31386 dated 23.01.2020. Fee paid Rs. 12000/- vide Slip No. 0816670 dated 20-01-2020, endorsed on 23.01.2020. Duplicate Dossier: Dy. No. 27115 dated 26.09.2022
	Pharmacological Group	ECTOPARASITICIDES, INCL. SCABICIDES ATC Code: P03AB02
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	50grams. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Lice-o-nil Cream Reg. No. 007705 M/s Wilson's Pharmaceuticals Islamabd.
	GMP status	Inspection conducted on 07.04.2014.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Section approval letter and copy of DML along with renewal status is required. iii. Evidence of product approval in RRA is required. iv. Label claim needs to be revised as per innovator product as it mentions excipients also. v. Finished product specifications are 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 conducted within last three years** • **Evidence of approval of required manufacturing facility i.e., "Cream section."** • **Submission of reference of specifications of finished product.** • **Confirmation of validity status of DML.**	
414.	Name and address of manufacturer/ Applicant	M/s IMCO Pharmaceutical Laboratories (Pvt.) Ltd. 73-Industrial Estate, Hayatabad, Peshawar. (DML No. 000317) Section.
	Brand Name + Dosage Form + Strength	M-NAC 50mg Tablet
	Composition	Each tablet contains; Diclofenac potassium…..50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 44 dated 14.03.2011 RnI verified. Initial fee Rs. 8000/- paid on 12.03.2011, endorsed on 14.03.2011 Differential fee: Dy. No. 31384 dated 23.01.2020. Fee paid Rs. 12000/- vide Slip No. 0816671 dated 20-01-2020, endorsed on 23.01.2020. Duplicate Dossier: Dy. No. 27115 dated 26.09.2022
	Pharmacological Group	Acetic acid derivatives and related substances ATC Code: M01AB05
	Type of Form	Form-5
	Finished product Specification	**Not mentioned.**
	Pack size & Demanded Price	20's. As per SRO.

	Approval status of product in Reference Regulatory Authorities	Diclofenac Potassium 50 mg Tablets - PL 20046/0078 MHRA Approved.
	Me-too status	Caflam 50mg Tablet Reg. No. 021528 M/s Novartis Pharma Karachi.
	GMP status	Inspection conducted on 07.04.2014.
	Remarks of the Evaluator	i. Latest GMP certificate/ inspection report is required. ii. Section approval letter and copy of DML along with renewal status is required. iii. Product approved in RRA is film coated, applied formulation is of uncoated tablet. Correction along with requisite fee is required. iv. Finished product specifications are required.
	Decision: Deferred for following; • **Latest GMP inspection report conducted within last three years** • **Revision of label as per innovator product along with submission of fee of Rs. 7,500/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Submission of reference of specifications of finished product.** • **Confirmation of validity status of DML.**	
415.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	ETHAZID 450mg+150mg Tablet
	Composition	Each tablet contains; Ethambutol …….400mg Isoniazid…….150mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 5380 dated 14.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.05.2011, endorsed on 14.05.2011 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777933 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis ATC Code: J04AM03
	Type of Form	Form-5
	Finished product Specification	**Pharmawise Specifications.**
	Pack size & Demanded Price	10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Ethozid Tablet Reg. No. 031092 M/s Pharmedic Pharma Lahore.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Evidence of approval in RRA is required. The firm vide letter No. nil dated 06.03.2023 has replied that the applied formulation is not approved in RRA.
	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.	
416.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Esol 20mg Capsule
	Composition	Each Capsule contains; Esomeprazole…… 20mg

	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 934 dated 10.03.2010 RnI verified. Initial fee Rs. 8000/- paid on 11.02.2010, endorsed on 10.03.2010 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777926 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	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	Esomeprazole 20mg Gastro-resistant Capsules (esomeprazole magnesium dihydrate) - PL 16028/0166. MHRA Approved.
	Me-too status	Nexum 20mg Capsule Reg. No. 033890 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Label claim needs to be revised as per innovator product along with submission of full fee. ii. Source of pellets is required. The firm vide letter No. nil dated 06.032023 has revised the label claim as under; Each capsule contains; Enteric coated pellets of esomeprazole magnesium trihydrate equivalent to esomeprazole ……20mg Source of pellets: M/s Vision Pharmaceuticals. Fee Rs. 30,000/- is paid for revisions vide slip No. 093651603282 dated 06.03.2023.
	Decision: Approved as per following label claim: **Each capsule contains;** **Enteric coated pellets of esomeprazole magnesium trihydrate equivalent to Esomeprazole ……20mg**	
417.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Esol 40mg Capsule
	Composition	Each Capsule contains; Esomeprazole…… 40mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 935 dated 10.03.2010 RnI verified. Initial fee Rs. 8000/- paid on 11.02.2010, endorsed on 10.03.2010 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777927 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	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	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT CAPSULES HARD.

		MHRA Approved.
	Me-too status	Nexum 40mg Capsule Reg. No. 033891 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Label claim needs to be revised as per innovator product along with submission of full fee. ii. Source of pellets is required. The firm vide letter No. nil dated 06.032023 has revised the label claim as under; Each capsule contains; Enteric coated pellets of esomeprazole magnesium trihydrate equivalent to esomeprazole ……40mg Source of pellets: M/s Vision Pharmaceuticals. Fee Rs. 30,000/- is paid for revisions vide slip No. 01021776 dated 06.03.2023.
	Decision: Approved as per following label claim: **Each capsule contains;** **Enteric coated pellets of esomeprazole magnesium trihydrate equivalent to Esomeprazole ……40mg**	
418.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Wisprazole 40mg Capsule
	Composition	Each Capsule contains; Omeprazole…… 40mg
	Diary No. Date of R & I & fee	<u>Initial dossier submission:</u> Dy. No. 5381 dated 14.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.05.2011, endorsed on 14.05.2011 <u>Differential fee:</u> Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777931 dated 22.01.2020, endorsed on (Not present) <u>Duplicate Dossier:</u> Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1x10's, 10x20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	OMEPRAZOLE/AYLOME/OMEANG 10MG, 20MG AND 40 MG GASTRO-RESISTANT CAPSULES, HARD PL 23218/0170-78 MHRA Approved.
	Me-too status	Risek 40mg Capsule Reg. no. 022109 M/s Getz Pharma Karach.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Label claim needs to be revised as per innovator product along with submission of full fee. ii. Source of pellets is required. The firm vide letter No. nil dated 06.032023 has revised the label claim as under; Each capsule contains; Omeprazole enteric coated pellets equivalent to Omeprazole ……40mg Source of pellets: M/s Vision Pharmaceuticals. Fee Rs. 30,000/- is paid for revisions vide slip No. 4237789059 dated 06.03.2023.

	Decision: Approved as per following label claim: **Each capsule contains;** **Each capsule contains;** **Omeprazole enteric coated pellets equivalent to Omeprazole ……40mg**	
419.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Mixirix 400mg Tablet
	Composition	Each film coated tablet contains; Moxifloxacin……400mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 932 dated 10.03.2010 RnI verified. Initial fee Rs. 8000/- paid on 11.02.2010, endorsed on 10.03.2010 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777928 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	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	KIMOKS 400 MG FILM-COATED TABLETS (MOXIFLOXACIN HYDROCHLORIDE) - PL 34088/0047; UK/H/6473/001/DC MHRA APPROVED.
	Me-too status	Avelox Tablets Reg. No. 024653 M/s Bayer Pakistan Ltd Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Label claim needs to be revised as per innovator product, as salt is not mentioned, along with submission of full fee. The firm vide letter No. nil dated 06.032023 has revised the label claim as under; Each film coated tablet contains; Moxifloxacin as HCl USP ……400mg Fee Rs. 30,000/- is paid for revisions vide slip No. 8229836721 dated 06.03.2023.
	Decision: Approved as per following label claim: **Each film coated tablet contains;** **Moxifloxacin as HCl USP ……400mg**	
420.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Phontan 500mg Tablet
	Composition	Each tablet contains; Mefenamic acid…….500mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 5379 dated 11.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.05.2011, endorsed on (Endorsement is crossed) Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777935 dated 22.01.2020, endorsed on (Not present)

		Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Fenamates ATC Code: M01AG01
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	1x10's 10x20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEFENAMIC ACID 500 MG FILM-COATED TABLETS - PL 13606/0258 MHRA Approved.
	Me-too status	Ponstan Forte tablet 500mg Reg. No. 006978 M/s Pfizer Laboratories Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. RRA Approved product is film coated, applied product is uncoated. Correction along with requisite fee is required. The firm vide letter No. nil dated 06.032023 has revised the label claim as under; Each film coated tablet contains; Mefenamic acid ……500mg Fee Rs. 7,500/- is paid for revisions vide slip No. 8229836721 dated 06.03.2023.
	Decision: Approved as per following label claim: **Each film coated tablet contains;** **Mefenamic acid ……500mg**	
421.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Fenowise 50mg Tablet
	Composition	Each film coated tablet contains; Diclofenac sodium…….50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 5382 dated 14.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 4.05.2011, endorsed on 14.05.2011 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777934 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	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	1x10's 10x20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Diclofenac Sodium 25 mg and 50 mg Gastro-resistant Tablets (diclofenac sodium) - PL 21880/0193-0194 MHRA Approved.
	Me-too status	Voltral 50mg Tablet Reg. No. 021525 M/s Novartis Pharma Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. RRA Approved product is gastro resistant/enteric coated, applied product is film coated. Correction along with requisite fee is required. The firm vide letter No. nil dated 06.032023 has revised the label claim as under; Each enteric coated tablet contains;

		Diclofenac sodium ……50mg Fee Rs. 7500/- is paid for revisions vide slip No. 4381391299 dated 06.03.2023.
	Decision: Approved as per following label claim: **Each enteric coated tablet contains;** **Diclofenac sodium ……50mg**	
422.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Oradine 10mg Tablet
	Composition	Each tablet contains; Loratadine…….50mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 5384 dated 14.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.05.2011, endorsed on 14.05.2011 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777936 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1x10's 10x20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Loratadine 10 mg Tablets - PL 25298/0117 MHRA Approved.
	Me-too status	Loratine Tablets Reg. No. 027640 M/s Delux Chemical Industries Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	
	Decision: Approved.	
423.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Cream/ Ointment/ Gel Section.
	Brand Name + Dosage Form + Strength	Myxin-B ointment
	Composition	Each gram contains; Polymixin B sulfate…..10000 units Bacitracin zinc……..…500 units
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 5385 dated 14.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.05.2011, endorsed on 14.05.2011 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777932 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	20gm. As per SRO.

	Approval status of product in Reference Regulatory Authorities	Could not be verified for topical ointment.
	Me-too status	Polyfax (for skin) Ointment Reg. No. 000371 M/s GSK Karachi.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Evidence of product approval in RRA is required. The firm vide letter No. nil dated 06.032023 has submitted reference of BACITRACIN ZINC AND POLYMYXIN B SULFATE-bacitracin zinc and polymyxi Bsulfate ointment E. Fougera & Co., A division of Nycomed US Inc. This reference is not verifiable and topical ointments with applied formulation are discontinued in USFDA.
	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.	
424.	Name and address of manufacturer/ Applicant	M/s PharmaWise Labs, 25-M QA Industrial Estate, Kot Lakhpat Lahore. (DML No. 000270) Oral Liquid (General) Section.
	Brand Name + Dosage Form + Strength	Codohyst Syrup
	Composition	Each 5mL contains; Ammonium chloride……..…100mg Pholcodine……....10mg Ephedrine HCl……...10mg Chlorpheniramine maleate…2mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 5383 dated 14.05.2011 RnI verified. Initial fee Rs. 8000/- paid on 14.05.2011, endorsed on 14.05.2011 Differential fee: Dy. No. (Not present) dated (Not present). Fee paid Rs. 12000/- vide Slip No. 0777937 dated 22.01.2020, endorsed on (Not present) Duplicate Dossier: Dy. No. 125/2022-R-II dated 25.10.2022
	Pharmacological Group	Cough Syrup.
	Type of Form	Form-5
	Finished product Specification	**Pharmawise Specifications.**
	Pack size & Demanded Price	60ml, 120ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Could not be verified.
	GMP status	Last inspection conducted on 18.10.2022. GMP certificate valid till 17.10.2025 is submitted.
	Remarks of the Evaluator	i. Evidence of product approval in RRA is required. ii. Evidence of me-too product is required. iii. Initially fee paid is of Codohyst-P Syrup. On Form-5, product Codohyst syrup is applied. The firm vide letter No. nil dated 06.032023 has submitted that evidence of product approval in RRA is not available.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	

Deferred Cases

425.	Name and address of manufacturer/ Applicant	M /s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi

	Brand Name + Dosage Form + Strength	Azicin Dry Powder Oral Suspension 200mg/5ml
	Composition	Each 5ml prepared suspension contains: 204.8mg Azithromycin monohydrate eq to azithromycin …200mg
	Diary No. Date of R & I & fee	Dy.No 11412 dated 05-03-2019, Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Macrolides. ATC Code: J01FA10
	Type of Form	Form 5.
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml, 30ml; As per SRO.
	Approval status of product in Reference Regulatory Authorities	Azithromycin 200mg/5ml powder for oral suspension MHRA Approved
	Me-too status	Palthro Dry Suspension 200mg/5ml by M/s Palpex Pharmaceuticals (Reg. No. 082947)
	GMP status	Last GMP inspection of the firm was conducted on 26-02-2019 and concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision of 296:	**Deferred for updated GMP status.**
	Remarks of the Evaluator	The Firm vide letter No. nil dated 22.12.2022 has submitted GMP certificate dated 20.12.2022 which is valid till 20.11.2024
	Decision: Approved.	
426.	Name and address of manufacturer/ Applicant	M /s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Lenox Tablet 4mg
	Composition	Each Film Coated Tablet Contains: Lornoxicam……4mg
	Diary No. Date of R & I & fee	Dy.No 11409 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's; 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	The firm was inspected on 28-09-2020 and conclusion of inspection was: In compliance to decision of 276th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/Sterile area. b) Prosecution in the Drug Court. c) Any other action taken by the concerned Board
	Remarks of the Evaluator	The firm submitted complete manufacturing outline
	Decision of 307:	**Deferred for updated status of GMP of the firm from QA & LT division**

	Remarks of the Evaluator	The Firm vide letter No. nil dated 22.12.2022 has submitted GMP certificate dated 20.12.2022 which is valid till 20.11.2024
	Decision: Approved.	
427.	Name and address of manufacturer/ Applicant	M /s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Lenox Tablet 8mg
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….8mg
	Diary No. Date of R & I & fee	Dy.No 11413 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5.
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg film-coated tablet (EMA approved)
	Me-too status	Xonica 8mg Tablet by M/s Zephyr Pharmatec (Reg#086983)
	GMP status	The firm was inspected on 28-09-2020 and conclusion of inspection was: In compliance to decision of 276th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/Sterile area. b) Prosecution in the Drug Court. c) Any other action taken by the concerned Board
	Remarks of the Evaluator	The firm submitted complete manufacturing outline
	Decision of 307:	**Deferred for updated status of GMP of the firm from QA & LT division**
	Remarks of the Evaluator	The Firm vide letter No. nil dated 22.12.2022 has submitted GMP certificate dated 20.12.2022 which is valid till 20.11.2024
	Decision: Approved.	
428.	Name and address of manufacturer/ Applicant	M /s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	E Dome Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Domperidone Maleate eq. to Domperidone …….10mg
	Diary No. Date of R & I & fee	Dy.No 11410 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5.
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	5x10's, 30'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	The firm was inspected on 28-09-2020 and conclusion of inspection was:

		In compliance to decision of 276th meeting of CLB, contravention of the Drugs Act, 1976 rules made there under, non-compliance of GMP conditions and non-compliance of conditions of the Drug Manufacturing License, you are hereby ordered to Show Cause Notice in writing as to why the following proceeding may not be initiated against you. a) Cancellation/Suspension of DML of Liquid Injectable/Sterile area. b) Prosecution in the Drug Court. c) Any other action taken by the concerned Board
	Remarks of the Evaluator	• The firm did not revise the label claim and master formulation from film coated to uncoated tablets as per reference formulation along with submission of applicable fee.
	Decision of 307th RB meeting:	**Deferred for following:** **• Revision of the label claim and master formulation from film coated to uncoated tablets as per reference formulation along with submission of applicable fee.** **• Updated status of GMP of the firm from QA & LT division.**
	Remarks of the Evaluator	The Firm vide letter No. nil dated nil has submitted GMP certificate dated 20.12.2022 which is valid till 20.11.2024. Further firm has stated that they have changed the reference brand to Motilium Tablet 10mg which is film coated. Therefore, no change in applied formulation is required nor any fee. The reference of firm is verifiable, Motilium 10 mg film-coated tablets are MHRA Approved.
	Decision: Approved.	
429.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	Navilox 400mg/250ml (IV)
	Composition	Each 250mL Vial Contains; Moxifloxacin HCl……..400mg
	Diary No. Date of R & I & fee	Dy. No. 15182 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0810047 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	In-house specifications.
	Pack size & Demanded Price	250mL x 1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Avelox 400 mg/250 ml solution for infusion MHRA Approved.
	Me-too status	Avelox Infusion Reg. No. 030851 M/s Bayer Pakistan (Pvt.) Ltd. Kot Lakhpat.
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. LVP Section approval of M/s Novamed is required is required. **The firm vide letter dated 24.11.2022 has submitted section approval letter of M/s**

		Novamed Pharmaceuticals (Pvt)Ltd. DML No. 000590, the section approval letter mentions "Liquid Injectable Ampoule/Vial General" section
	Decision of 323rd RB	Deferred for provision of evidence of availability of manufacturing facility for applied fill volume.
	Remarks of the Evaluator	The firm vide letter No. GP-024/23 dated 06.02.2023 has submitted evidence of vial filling machine having capacity to fill and seal vials of 100ml to 300ml volume. M/s Novamed is already manufacturing X-Lox infusion 400mg/250ml
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.	
430.	Name and address of manufacturer/ Applicant	M/s. Dyson Research Laboratories, 28-KM, Ferozpur Road, Lahore (Contract Giver) (DML No. 000559). Contract with M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Ampoule (General) Section
	Brand Name + Dosage Form + Strength	Ondsave 8mg/4ml Injection
	Composition	Each 4ml Ampoule contains; Ondansetron hydrochloride dihydrate….8mg
	Diary No. Date of R & I & fee	Dy.No.40251 dated 05.12.2018; Fee Rs. 50,000/- paid vide slip No. 0821306 dated 05.12.18, Fee slip is not endorsed. Duplicate dossier submitted vide Dy. No. 33010 dated 17.11.2022, Diary verified from RnI.
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists ATC Code: A04AA01
	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	ONDANSETRON 8MG/4ML INJECTION (ONDANSETRON HYDROCHLORIDE) PL 04543/0508 MHRA APPROVED.
	Me-too status	Periset 4ml injection Reg. No. 090250 M/s Linear Pharma Islamabad.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	i. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. ii. Copy of fee slip does not have endorsement stamp. Copy of endorsed deposit slip is required. iii. The label claim applied includes amount of salt and hydrate, reference products mention strength of base. Correction along with submission of full fee i.e. Rs.75000/- is required.
	Decision of 324th RB	**Decision: Approved as per following label claim:** **"Each 4ml Ampoule contains;** **Ondansetron as hydrochloride dihydrate….8mg"** **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.** **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 Km, Lahore Sharikpur Road, Sheikhupura along with**

		verification of fee challan as per decision of 285th meeting of Registration Board.
	Remarks of the Evaluator	The firm vide letter No. DRL/RA/0720-378 dated 02.03.2023 has informed that they have applied for contract manufacturing from M/s Medisave Pharmaceuticals, Plot No. 578-579, Sunder Industrial Estate, Raiwind Road, Lahore. It has been checked and verified that M/s Dyson Research Laboratories Had applied for contract from M/s Medisave Pharmaceuticals, Plot No. 578-579, Sunder Industrial Estate, Raiwind Road, Lahore for this product, but inadvertently contract from M/s McOlson was mentioned as a typographic error.
	Decision: Approved for contract manufacturing from M/s Medisave Pharmaceuticals, Plot No. 578-579, Sunder Industrial Estate, Raiwind Road, Lahore .	
431.	Name and address of manufacturer/ Applicant	**M/s Theramed pharamaceuticals (pvt) Ltd, 45-Km Multan Road Lahore Pakistan** Contract Manufactured by **M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad,Peshawar**
	Brand Name + Dosage Form + Strength	Thrafor 100mg/5ml Injection
	Composition	Each 5ml contains: Iron III Hydroxide Sucrose Complex ….....100mg
	Diary No. Date of R & I & fee	Dy.No.20169; 06-11-2017; Rs.50,000/- (06-11-2017)
	Pharmacological Group	Anti-anemic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	5ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Suciron Injection of M/s Saffron Pharmaceuticals (Reg No# 064665)
	GMP status	Last GMP inspection of Theramed Pharmaceuticals is conducted on 10- 10- 17 and the report concludes that panel recommends grant of renewal of DML and Certificate of cGMP dated . 10-10-2017 & Last GMP inspection of Astellas Pharmaceuticals conducted on 02-10-2017 and the report concludes that overall the firm was operating is satisfactory level of cGMP
	Remarks of the Evaluator	□□. No of Sections of Theramed : 6 □□Contract agreement : Attached □□No of already registered contract manufactured i. products: In 282nd meeting 19 products approved
	Decision of 285th RB	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 26.01.2023 has submitted capacity assessment inspection report of M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad, Peshawar dated 02.09.2020. The report was presented before the board in its 297th meeting. The board the Board decided to allow contract manufacturing from M/s Astellas pharmaceutical (Pvt.) Ltd, 15-C, Hayatabad Industrial Estate, Peshawar for following sections:

		• Dry Powder Injectable (Cephalosporin) • Liquid Injection (Ampoule General) • Liquid Injection (Vial General) SVP, LVP
	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.	
432.	Name and address of manufacturer/ Applicant	**M/s Theramed pharamaceuticals (pvt) Ltd, 45-Km Multan Road Lahore Pakistan** Contract Manufactured by **M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad,Peshawar**
	Brand Name + Dosage Form + Strength	Therozolid 400mg/200ml IV Infusion
	Composition	Each 200ml contains: Linezolid.....400mg
	Diary No. Date of R & I & fee	Dy.No.20167; 06-11-2017; Rs.50,000/- (06-11-2017)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	200ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX linezolid 400mg/200mL injection infusion bag of (USFDA approved.)
	Me-too status	Linzol Infusion 400mg of M/s Regal Pharmaceuticals
	GMP status	Last GMP inspection of Theramed Pharmaceuticals is conducted on 10- 10- 17 and the report concludes that panel recommends grant of renewal of DML and Certificate of cGMP dated . 10-10-2017 & Last GMP inspection of Astellas Pharmaceuticals conducted on 02-10-2017 and the report concludes that overall the firm was operating is satisfactory level of cGMP
	Remarks of the Evaluator	□□ No of Sections of Theramed : 6 □□Contract agreement : Attached □□No of already registered contract manufactured ii. products: In 282nd meeting 19 products approved
	Decision of 285th RB	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 26.01.2023 has submitted capacity assessment inspection report of M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad, Peshawar dated 02.09.2020. The report was presented before the board in its 297th meeting. The board the Board decided to allow contract manufacturing from M/s Astellas pharmaceutical (Pvt.) Ltd, 15-C, Hayatabad Industrial Estate, Peshawar for following sections: • Dry Powder Injectable (Cephalosporin) • Liquid Injection (Ampoule General) • Liquid Injection (Vial General) SVP, LVP
	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.	
433.	Name and address of manufacturer/ Applicant	**M/s Theramed pharamaceuticals (pvt) Ltd, 45-Km Multan Road Lahore Pakistan** Contract Manufactured by

		M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad,Peshawar
	Brand Name + Dosage Form + Strength	Theramox 400mg/250ml Infusion
	Composition	250 ml of solution contains: Moxifloxacine as Hydrochloride……400mg
	Diary No. Date of R & I & fee	Dy.No.20170; 06-11-2017; Rs.50,000/- (06-11-2017)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Avelox solution for infusion of (MHRA approved)
	Me-too status	Moximed solution for infusion of M/s Medimarker's
	GMP status	Last GMP inspection of Theramed Pharmaceuticals is conducted on 10- 10- 17 and the report concludes that panel recommends grant of renewal of DML and Certificate of cGMP dated . 10-10-2017 & Last GMP inspection of Astellas Pharmaceuticals conducted on 02-10-2017 and the report concludes that overall the firm was operating is satisfactory level of cGMP
	Remarks of the Evaluator	No of Sections of Theramed : 6 Contract agreement : Attached No of already registered contract manufactured iii. products: In 282nd meeting 19 products approved
	Decision of 285th RB	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 26.01.2023 has submitted capacity assessment inspection report of M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad, Peshawar dated 02.09.2020. The report was presented before the board in its 297th meeting. The board the Board decided to allow contract manufacturing from M/s Astellas pharmaceutical (Pvt.) Ltd, 15-C, Hayatabad Industrial Estate, Peshawar for following sections: • Dry Powder Injectable (Cephalosporin) • Liquid Injection (Ampoule General) • Liquid Injection (Vial General) SVP, LVP
	Decision: Approved.	
434.	Name and address of manufacturer/ Applicant	**M/s Theramed pharamaceuticals (pvt) Ltd, 45-Km Multan Road Lahore Pakistan** Contract Manufactured by **M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad,Peshawar**
	Brand Name + Dosage Form + Strength	Thera-K 10mg/ml Injection
	Composition	Each Ampoule contains: Phytomenadione U.S.P (Vitamin K)…….....10mg
	Diary No. Date of R & I & fee	Dy.No.20171; 06-11-2017; Rs.50,000/- (06-11-2017)
	Pharmacological Group	Vitamin K
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Vitamin k1 of USFDA approved
	Me-too status	Kaplor Injection of M/s P.D.H Laboratories
	GMP status	Last GMP inspection of Theramed Pharmaceuticals is conducted on 10- 10- 17 and the report concludes that panel recommends grant of renewal of DML and Certificate of cGMP dated . 10-10-2017 & Last GMP inspection of Astellas Pharmaceuticals conducted on 02-10-2017 and the report concludes that overall the firm was operating is satisfactory level of cGMP
	Remarks of the Evaluator	No of Sections of Theramed : 6 Contract agreement : Attached No of already registered contract manufactured i. products: In 282nd meeting 19 products approved
	Decision of 285th RB	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 26.01.2023 has submitted capacity assessment inspection report of M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad, Peshawar dated 02.09.2020. The report was presented before the board in its 297th meeting. The board the Board decided to allow contract manufacturing from M/s Astellas pharmaceutical (Pvt.) Ltd, 15-C, Hayatabad Industrial Estate, Peshawar for following sections: • Dry Powder Injectable (Cephalosporin) • Liquid Injection (Ampoule General) • Liquid Injection (Vial General) SVP, LVP
	Decision: Approved.	
435.	Name and address of manufacturer/ Applicant	**M/s Theramed pharamaceuticals (pvt) Ltd, 45-Km Multan Road Lahore Pakistan** Contract Manufactured by **M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad,Peshawar**
	Brand Name + Dosage Form + Strength	Theraquin 200mg/100ml IV Infusion
	Composition	Each Vial contains: Ciprofloxacin Lactate U.S.P eq to Ciprofloxacin ….....200mg/100ml
	Diary No. Date of R & I & fee	Dy.No.20168; 06-11-2017; Rs.50,000/- (06-11-2017)
	Pharmacological Group	Floroquinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	100ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin 2 mg/ml Solution for Infusion by M/s Hospira UK Ltd (MHRA)
	Me-too status	Reflox Infusion of M/s Regal Pharmaceutical
	GMP status	Last GMP inspection of Theramed Pharmaceuticals is conducted on 10- 10- 17 and the report concludes that panel recommends grant of renewal of DML and Certificate of cGMP dated . 10-10-2017 & Last GMP inspection of Astellas Pharmaceuticals conducted on 02-10-2017 and the report concludes that overall the firm was operating is satisfactory level of

		cGMP
	Remarks of the Evaluator	□□ No of Sections of Theramed : 6 □□Contract agreement : Attached □□No of already registered contract manufactured ii. products: In 282nd meeting 19 products approved
	Decision of 285th RB	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. nil dated 26.01.2023 has submitted capacity assessment inspection report of M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad, Peshawar dated 02.09.2020. The report was presented before the board in its 297th meeting. The board the Board decided to allow contract manufacturing from M/s Astellas pharmaceutical (Pvt.) Ltd, 15-C, Hayatabad Industrial Estate, Peshawar for following sections: • Dry Powder Injectable (Cephalosporin) • Liquid Injection (Ampoule General) • Liquid Injection (Vial General) SVP, LVP
	Decision: Approved.	
436.	Name and address of manufacturer/ Applicant	**M/s Theramed pharamaceuticals (pvt) Ltd, 45-Km Multan Road Lahore Pakistan** Contract Manufactured by **M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad,Peshawar**
	Brand Name + Dosage Form + Strength	Theravit injection 5mg/ml
	Composition	Each ml contains: Cholecalciferol……..5mg (200,000 IU)
	Diary No. Date of R & I & fee	Dy.No.20172; 06-11-2017; Rs.50,000/- (06-11-2017)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	Calciferol Injection M/s Global Pharmaceuticals,
	GMP status	Last GMP inspection of Theramed Pharmaceuticals is conducted on 10- 10- 17 and the report concludes that panel recommends grant of renewal of DML and Certificate of cGMP dated . 10-10-2017 & Last GMP inspection of Astellas Pharmaceuticals conducted on 02-10-2017 and the report concludes that overall the firm was operating is satisfactory level of cGMP
	Remarks of the Evaluator	□□ No of Sections of Theramed : 6 □□Contract agreement : Attached □□No of already registered contract manufactured iii. products: In 282nd meeting 19 products approved
	Decision of 285th RB	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**

	Remarks of the Evaluator	The firm vide letter No. nil dated 26.01.2023 has submitted capacity assessment inspection report of M/s Astellas Pharmaceuticals (pvt) Ltd. 15- C Industrial Estate, Hayatabad, Peshawar dated 02.09.2020. The report was presented before the board in its 297th meeting. The board the Board decided to allow contract manufacturing from M/s Astellas pharmaceutical (Pvt.) Ltd, 15-C, Hayatabad Industrial Estate, Peshawar for following sections: • Dry Powder Injectable (Cephalosporin) • Liquid Injection (Ampoule General) • Liquid Injection (Vial General) SVP, LVP
	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.	
437.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	Active-DM Syrup (Dextromethorphen 10 mg, Pseudoephedrine HCl 30 mg)
	Composition	Each 5ml contains; Dextromethorphan Hydrobromide…..... 10 mg Pseudoephdrine Hydrochloride …….. 30 mg Triprolidine hydrochloride……. 1.25 mg
	Dairy No. date of R &I fee	Dy. No. 15307 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835975 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antihistamines for systemic use ATC code: R06AX07
	Type of form	Form-5A
	Finished product specifications	Not mentioned.
	Pack size and Demand Price	60 ml, as per SRO
	Approval status of product in Reference Regulatory Authorities	Multi-Action ACTIFED Dry Coughs (oral Liquid) MHRA approved
	Me-too-status	Actifed DM Cough Syrup Reg. No. 007817 M/s GSK west Warf Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i.The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5. ii. Specifications of finished product are not mentioned in the application.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of proper specifications.**
	Remark of the Evaluator.	i. The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 03646196 dated 23.02.2023. ii. Specifications of finished product are revised to USP Specifications.
	Decision: Approved with USP specifications.	
438.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form andStrength	AMPITOR 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Atorvastatin as Calcium trihydrate…..10mg
	Dairy No. date of R &I fee	Dy. No. 15257 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818375 dated 07.03.2019

	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA05
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor 10mg, 20mg, 40mg 80mg USFDA Approved.
	Me-too-status	Lipitor Tablet 10mg Reg. No. 023620 M/s Pfizer Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of applied product is available in USP and applied specifications are innovator's. Justification or change of specifications is required along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.**
	Remark of the Evaluator.	i. The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 88129925445 dated 23.02.2023. ii. Specifications of finished product are revised to USP Specifications.
	Decision: Approved with USP specifications.	
439.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMPITOR 20mg Tablet
	Composition	Each Film Coated Tablet Contains; Atorvastatin as Calcium trihydrate…..20mg
	Dairy No. date of R &I fee	Dy. No. 15252 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818374 dated 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA05
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor 10mg, 20mg, 40mg 80mg USFDA Approved.
	Me-too-status	Lipitor Tablet 20mg Reg. No. 023621 M/s Pfizer Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of applied product is available in USP and applied specifications are innovator's. Justification or change of specifications is required along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.**
	Remark of the Evaluator.	i. The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 70717783297 dated 23.02.2023.

		ii. Specifications of finished product are revised to USP Specifications.
	Decision: Approved with USP specifications.	
440.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMPITOR 40mg Tablets.
	Composition	Each Film Coated Tablet Contains; Atorvastatin as Calcium trihydrate …..40mg
	Dairy No. date of R &I fee	Dy. No. 15248 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818368 dated 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA05
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor 10mg, 20mg, 40mg 80mg USFDA Approved.
	Me-too-status	Lipitor Tablet 40mg Reg. No. 023622 M/s Pfizer Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of applied product is available in USP and applied specifications are innovator's. Justification or change of specifications is required along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.**
	Remark of the Evaluator.	i. The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 39906552382 dated 23.02.2023. ii. Specifications of finished product are revised to USP Specifications.
	Decision: Approved.	
441.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	AMROKET 30 MG INJECTION (Ampoule) (For toll manufacturing)
	Composition	Each Ampoule Contains; Ketorolac tromethamine ……. 30 mg
	Dairy No. date of R &I fee	Dy. No. 15373 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836427 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB15
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	1x1 As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved
	Me-too-status	Toralac Injection 30mg Reg. No. 050290 M/s Global Pharma Islamabad.

	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Contract manufacturing details are not provided and on application form Toll manufacturing is mentioned. iii. Volume of ampoule is not mentioned. It needs to be defined along with submission of requisite fee (Full Fee).
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of details of applied product i.e. formulation, label, container closure system etc.** • **Submission of clarification why contract manufacturing is mentioned in the application.**
	Remark of the Evaluator.	i. The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 94348879 dated 23.02.2023. ii. Specifications of finished product are revised to USP Specifications. iii. The firm has stated that its for local manufacturing, toll manufacturing is written by mistake. iv. The label is revised as under; Each 1ml Ampoule contains; Ketorolac Tromethamine…… 30mg. (1mL vial is approved in health Canada)
	Decision: Approved.	
442.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AM-TOP 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains; Pantoprazole as sodium sesquihydrate…… 20mg
	Dairy No. date of R &I fee	Dy. No. 15346 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836439 dated 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 20 and 40mg gastro-resistant tablet; PL 49445/0026; PL 49445/0027 MHRA Approved.
	Me-too-status	Neege 20mg Tablet Reg. No. 079531 M/s Sami Pharmaceuticals (Pvt) Ltd Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 7136941898 dated 23.02.2023.
	Decision: Approved.	
443.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)

	Brand Name + Dosage Form and Strength	AM-TOP 40mg Tablet
	Composition	Each Enteric Coated Tablet Contains; Pantoprazole as sodium sesquihydrate…… 40mg
	Dairy No. date of R &I fee	Dy. No. 15340 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836433 dated 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC02
	Type of form	Form 5-A
	Finished product specifications	USP Specifiations
	Pack size and Demand Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 20 and 40mg gastro-resistant tablet; PL 49445/0026; PL 49445/0027 MHRA Approved.
	Me-too-status	Neege 40mg Tablet Reg. No. 039504 M/s Sami Pharmaceuticals (Pvt) Ltd Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 178937601270 dated 23.02.2023.
	Decision: Approved.	
444.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	BALIN 50 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..50 mg
	Dairy No. date of R &I fee	Dy. No. 15277 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829593 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand 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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 287867570 dated 23.02.2023.
	Decision: Approved with BP specifications.	
445.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406)

		Capsule Section (General)
	Brand Name + Dosage Form and Strength	BALIN 150 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..150 mg
	Dairy No. date of R &I fee	Dy. No. 15313 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835982 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica® 150 mg hard capsules MHRA Approved.
	Me-too-status	Gabica 150 mg Capsule Reg. No. 048724 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 896350547717 dated 23.02.2023.
	Decision: Approved with BP specifications.	
446.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	BALIN 75 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..75 mg
	Dairy No. date of R &I fee	Dy. No. 15312 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835981 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand 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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 6871664062 dated 23.02.2023.

	Decision: Approved with BP specifications.	
447.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	BALIN 300 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..300 mg
	Dairy No. date of R &I fee	Dy. No. 15314 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835983 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand 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	Inspection report dated 18.07.2018 is attached which is older than 3 years.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 42349404723 dated 23.02.2023.
	Decision: Approved with BP specifications.	
448.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	COXIB 200mg Capsule
	Composition	Each Capsule Contains; Celecoxib …….200mg
	Dairy No. date of R &I fee	Dy. No. 15235 dated 07.03.2019. Fee paid vide voucher No. 0758799 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Coxibs. ATC Code: M01AH01
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Celecoxib 100 mg capsules, hard and Celecoxib 200 mg capsules, hard (celecoxib) - PL 35507/0133 -0134 MHRA Approved.
	Me-too-status	Colixib Capsule 200mg Reg. No. 100505 M/s High-Q Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 611042416967 dated 23.02.2023.

	Decision: Approved with BP specifications.	
449.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	COXIB 100mg Capsule
	Composition	Each Capsule Contains; Celecoxib …… 100 mg
	Dairy No. date of R &I fee	Dy. No. 15236 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0758800 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Coxibs. ATC Code: M01AH01
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CELEBREX 100-mg capsules FDA Approved
	Me-too-status	Celbex Capsules 100mg Reg. No. 028694 M/s Getz Pharma (Pvt) Ltd., 29-30 Sector 27 Korangi Industrial Area Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5. ii. In product summary dosage form is mentioned as "oral 100mg per tablet"
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of proper formulation and strength of applied product.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 with proper formulation along with fee of Rs. 30,000/- vide slip no. 411349324298 dated 23.02.2023.
	Decision: Approved with BP specifications.	
450.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Ear/Eye Drop Section (General)
	Brand Name + Dosage Form and Strength	GENTAMYCIN HC DROPS 0.3%/1%
	Composition	Each 100ml Contains; Gentamycin Sulphate eq. to Gentamycin…… 0.3%W/V Hydrocortisone Acetate……..1.0% W/V
	Dairy No. date of R &I fee	Dy. No. 15355 dated 07.03.2019. Fee paid vide voucher No. 0836413 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Corticosteroids and antiinfectives in combination. ATC Code: S03CA04
	Type of form	Form-5-A
	Finished product specifications	Not mentioned.
	Pack size and Demand Price	5ml. as per SRO
	Approval status of product in Reference Regulatory Authorities	GENTAMICIN 0.3% W/V AND HYDROCORTISONE ACETATE 1% W/V EAR DROPS, GENTISONE HC EAR DROPS MHRA Approved.
	Me-too-status	Otogen HC Ear Drops Reg. No. 016662 M/s Remington Pharmaceuticals Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate

		valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Specifications of finished product are not defined. ii. Pack size if of 5 ml and label claim is made of 100ml, justification or correction is required along with submission of requisite fee. iii. The pack size of RRA approved product is 10ml, justification for applied pack size is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of specifications of the applied product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 with proper formulation along with fee of Rs. 30,000/- vide slip no. 16537453694 dated 23.02.2023. • The firm has stated that finished product specifications will be of USP. • Evidence of MHRA is provided as evidence of product approval in RRA.
	Decision: Approved with BP specifications.	
451.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 2.0 mg Tablet
	Composition	Each Film coated Tablet contains; Glimepiride …….. 2 mg
	Dairy No. date of R &I fee	Dy. No. 15272 dated 07.03.2019. Fee paid vide voucher No. 0829587 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Revision of formulation as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 with proper formulation along with fee of Rs. 30,000/- vide slip no. 929386143 dated 23.02.2023.

		• The firm has stated that finished product specifications will be of USP. • The firm has revised formulation from coated to uncoated tablet. The revised label claim is reproduced below; Each tablet contains; Glimepiride…….2.0mg
	Decision: Approved as per following label claim with USP specifications: **Each tablet contains:** **Glimepiride…….2.0mg**	
452.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 3.0 mg Tablet
	Composition	Each Film coated Tablet contains; Glimepiride …….. 3 mg
	Dairy No. date of R &I fee	Dy. No. 15271 dated 07.03.2019. Fee paid vide voucher No. 0829586 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 3 mg Tablets MHRA Approved.
	Me-too-status	Amaryl tab 3 mg Reg. No. 021094 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Revision of formulation as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 with proper formulation along with fee of Rs. 30,000/- vide slip no. 6328846499 dated 23.02.2023. • The firm has stated that finished product specifications will be of USP. • The firm has revised formulation from coated to uncoated tablet. The revised label claim is reproduced below; Each tablet contains; Glimepiride…….3.0mg
	Decision: Approved as per following label claim with USP specifications: **Each tablet contains:** **Glimepiride…….3.0mg**	
453.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 4.0 mg Tablet

	Composition	Each Film coated Tablet contains; Glimepiride …….. 4 mg
	Dairy No. date of R &I fee	Dy. No. 15270 dated 07.03.2019. Fee paid vide voucher No. 0829585 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 4 mg Tablets MHRA Approved.
	Me-too-status	Amaryl tab 4 mg Reg. No. 021095 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Revision of formulation as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 with proper formulation along with fee of Rs. 30,000/- vide slip no. 71437095814 dated 23.02.2023. • The firm has stated that finished product specifications will be of USP. • The firm has revised formulation from coated to uncoated tablet. The revised label claim is reproduced below; Each tablet contains; Glimepiride…….4.0mg
	Decision: Approved as per following label claim with USP specifications: **Each tablet contains:** **Glimepiride…….4.0mg**	
454.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	LO-HARD 50mg/12.5mg Tablet
	Composition	Each film coated tablet contains; Losartan Potassium …… 50 mg Hydrochlorothiazide…… 12.5 mg
	Dairy No. date of R &I fee	Dy. No. 15284 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829600 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics. ATC Code: C09DA01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory	LOSARTAN POTASSIUM /HYDROCHLOROTHIAZIDE 50MG /12.5MG TABLETS (Film Coated)

	Authorities	MHRA Approved.
	Me-too-status	Thaitan-H 50mg/12.5mg Tablet Reg. No. 104788 M/s Jaens Pharmaceutical Industries (Pvt.) Ltd. Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 9939196060 dated 23.02.2023.
	Decision: Approved.	
455.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	LO-HARD 100mg/12.5mg Tablet
	Composition	Each film coated tablet contains; Losartan Potassium …… 100 mg Hydrochlorothiazide…… 12.5 mg
	Dairy No. date of R &I fee	Dy. No. 15247 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0801927 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics. ATC Code: C09DA01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COZAAR-COMP 100MG/12.5MG FILM-COATED TABLETS MHRA Approved.
	Me-too-status	Losmart-H 100mg/12.5mg Tablet Reg. No. 100198 M/s Scilife Pharma (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 04789197791 dated 23.02.2023.
	Decision: Approved.	
456.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MATA PLUS Tablet 50mg/1000mg
	Composition	Each Film Coated Tablet Contains; Sitagliptin as Phosphate monohydrate…… 50mg Metformin HCl……..... 1000mg
	Dairy No. date of R &I fee	Dy. No. 15244 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0801925 dated 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs

		ATC Code: A10BD07
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand 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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 9494007889 dated 23.02.2023.
	Decision: Approved.	
457.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MATA PLUS Tablet 50mg/500mg
	Composition	Each Film Coated Tablet Contains; Sitagliptin as Phosphate monohydrate…… 50mg Metformin HCl……..... 500mg
	Dairy No. date of R &I fee	Dy. No. 15237 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0758993 dated 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD07
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet Tablets MHRA Approved.
	Me-too-status	Treviamet 50mg 500mg Tablet Reg. No. 055443 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 403714967 dated 23.02.2023.
	Decision: Approved.	
458.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MEPRA 20mg Capsule
	Composition	Each Capsule Contains; Esomeprazole Magnesium trihydrate eq. Esomeprazole 22.5% pellets …20mg
	Dairy No. date of R &I fee	Dy. No. 15282 dated 07.03.2019. Fee paid Rs. 80,000/- vide voucher No. 0836445 dated 05.03.2019, endorsed on 07.03.2019 Fee paid Rs. 20,000/- vide voucher No. 0752860 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton Pump inhibitors.

		ATC Code: A02BC05
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Esomeprazole 20mg Gastro-resistant Capsules (esomeprazole magnesium dihydrate) - PL 16028/0166. MHRA Approved.
	Me-too-status	Nexum 20mg Capsule Reg. No. 033890 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Source of pellets is required. ii. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of source of pellets.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 612355222781 dated 23.02.2023. • Source of pellets is not mentioned
	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.**	
459.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MEPRA 40mg Capsule
	Composition	Each Capsule Contains; Esomeprazole Magnesium trihydrate eq. Esomeprazole 22.5% pellets …40mg
	Dairy No. date of R &I fee	Dy. No. 15239 dated 07.03.2019. Fee paid Rs. 80,000/- vide voucher No. 0836446 dated 05.03.2019, endorsed on 07.03.2019 Fee paid Rs. 20,000/- vide voucher No. 0758995 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT CAPSULES HARD. MHRA Approved.
	Me-too-status	Nexum 40mg Capsule Reg. No. 033891 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Source of pellets is required. ii. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of source of pellets.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 9376776872 dated 23.02.2023. • Source of pellets is not mentioned

	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.**	
460.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Metro 200mg Tablet
	Composition	Each film coated tablet Contains; Metronidazole B.P. …… 200mg
	Dairy No. date of R &I fee	Dy. No. 15368 dated 07.03.2019. Fee paid vide voucher No. 0836422 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Agents Against Amoebiasis And Other Protozoal Diseases, Nitroimidazole Derivatives. ATC Code: P01AB01
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metronidazole 200 mg Tablets Film-coated tablets MHRA Approved
	Me-too-status	Flagyl Tablets 200mg Reg. No. 000910
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 3452199256 dated 23.02.2023.
	Decision: Approved.	
461.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	METRO 400mg Tablet
	Composition	Each film coated tablet Contains; Metronidazole B.P. …… 400mg
	Dairy No. date of R &I fee	Dy. No. 15364 dated 07.03.2019. Fee paid vide voucher No. 0836418 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Agents Against Amoebiasis And Other Protozoal Diseases, Nitroimidazole Derivatives. ATC Code: P01AB01
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand 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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**

	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 76136588 dated 23.02.2023.
	Decision: Approved.	
462.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	METRO 200 mg/5ml Suspension
	Composition	Each 5mL contains; Metronidazole …….... 200 mg
	Dairy No. date of R &I fee	Dy. No. 15374 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836428 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antibacterial for Systemic use. ATC Code: J01XD01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metronidazole 200 mg/5 ml Oral Suspension Each 5 ml of oral suspension contains metronidazole benzoate equivalent to 200 mg of metronidazole MHRA Approved.
	Me-too-status	Diagyl Suspension Reg. No. 020229 M/s Swiss Pharmaceuticals (Pvt) Ltd., A-159 SITE North Karachi Scheme No. 33 Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Salt is not mentioned in label claim.
	Decision of 323rd RB	**Decision: Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Correction for salt of API as per innovator product.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 7678236527 dated 23.02.2023. The firm has revised the label as under; Each 5ml contains; Mteronidazole as benzoate……..200mg
	Decision: Approved as per following label claim: **"Each 5ml contains;** **Mteronidazole as benzoate……..200mg"**	
463.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MLODI 5mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine Besylate ……. 5 mg
	Dairy No. date of R &I fee	Dy. No. 15241 dated 07.03.2019. Fee paid vide voucher No. 0758998 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Dihydropyridine derivatives ATC Code: C08CA01
	Type of form	Form-5-A
	Finished product specifications	In-House Specifications (Page 104)
	Pack size and Demand Price	As per DRAP Policy

	Approval status of product in Reference Regulatory Authorities	Norvasc 5 mg Tablets (amlodipine besylate equivalent to 5 mg of amlodipine per tablet). FDA Approved
	Me-too-status	Norvasc Tablet 5mg Reg. No. 011825 M/s Pfizer Pakistan Ltd., B-2-SITE Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The specifications of the applied product are present in pharmacopoeia and specifications applied are mfg specifications. This needs correction along with requisite fee. iii. The product of innovator is not film coated and the applied product is film coated. Justification is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Revision of formulation as per innovator product.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 537931685908 dated 23.02.2023. The firm has revised the label as under; Each tablet contains; Amlodipine (as besylate)……..5mg
	Decision: Approved as per following label claim with USP specifications: **Each tablet contains;** **Amlodipine (as besylate)……..5mg**	
464.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MLODI 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine Besylate ……. 10 mg
	Dairy No. date of R &I fee	Dy. No. 15233 dated 07.03.2019. Fee paid vide voucher No. 0758797 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Dihydropyridine derivatives ATC Code: C08CA01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Norvasc 10 mg Tablets (amlodipine besylate equivalent to 5 mg of amlodipine per tablet). FDA Approved
	Me-too-status	Norvasc Tablet 10mg Reg. No. 011826 M/s Pfizer Pakistan Ltd., B-2-SITE Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The specifications of the applied product are present in pharmacopoeia and specifications applied are mfg specifications. This needs correction along with requisite fee. iii. The product of innovator is not film coated and the applied product is film coated. Justification is required.

	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,** • **Submission of formulation and label claim as per innovator product.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted correct Form-5 along with fee of Rs. 30,000/- vide slip no. 0614336584 dated 23.02.2023. The firm has revised the label as under; Each tablet contains; Amlodipine (as besylate)……..10mg
	Decision: Approved as per following label claim with USP specifications: **Each tablet contains;** **Amlodipine (as besylate)……..10mg**	
465.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET-D 60mg/120mg Tablet
	Composition	Each Film Coated Tablet Contains; Fexofenadine Hydrochloride USP ……60 mg Pseudoephedrine Hydrochloride USP …….. 120 mg
	Dairy No. date of R &I fee	Dy. No. 15306 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835974 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	pseudoephedrine, combinations ATC Code: R01BA52
	Type of form	Form-5
	Finished product specifications	Amros Specifications
	Pack size and Demand Price	1 x 10's 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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Approval of product in Reference Regulatory Authorities is required.
	Decision of 323rd RB	**Deferred for evidence of approval of applied formulation in reference regulatory**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has revised label claim as per innovator product along with fee of Rs. 30,000/- vide slip no. 0614336584 dated 23.02.2023. The firm has revised the label as under; Each extended release tablet contains; Fexofenadine Hydrochloride ……60 mg Pseudoephedrine Hydrochloride.. 120 mg
	Decision: Approved as per following label claim with USP specifications: **Each extended release tablet contains;** **Fexofenadine Hydrochloride ……60 mg** **Pseudoephedrine Hydrochloride.. 120 mg**	
466.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)

	Brand Name + Dosage Form and Strength	NEXET 60mg Tablet
	Composition	Each Tablet Contains; Fexofenadine HCl……..60mg
	Dairy No. date of R &I fee	Dy. No. 15342 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836435 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX26
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ALLEGRA 60mg Film-coated Tablets USFDA Approved.
	Me-too-status	Fexet Tablet 60mg Reg. No. 029434 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,** • **Submission of revised formulation as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 932829277377 dated 23.02.2023. • The firm has not revised the formulation (uncoated to coated).
	Decision: Approved with following label; **Each film coated tablet contains;** **Fexofenadine HCl……..60mg** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
467.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET 120mg Tablet
	Composition	Each Tablet Contains; Fexofenadine HCl……..120mg
	Dairy No. date of R &I fee	Dy. No. 15341 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836434 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX26
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine Hydrochloride 120 mg and 180 mg Film-coated tablets PL 21880/0259-0260; UK/H/7053/002-003/DC MHRA Approved.

	Me-too-status	Fexet Tablet 120mg Reg. No. 029435 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,** • **Submission of revised formulation and label as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 374282416477 dated 23.02.2023. • The firm has not revised the formulation (uncoated to coated).
	Decision: Approved with following label; **Each film coated tablet contains;** **Fexofenadine HCl……..120mg** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
468.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET 180mg Tablet
	Composition	Each Tablet Contains; Fexofenadine HCl……..180mg
	Dairy No. date of R &I fee	Dy. No. 15343 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836436 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX26
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine Hydrochloride 120 mg and 180 mg Film-coated tablets PL 21880/0259-0260; UK/H/7053/002-003/DC MHRA Approved.
	Me-too-status	Fexet Tablet 180mg Reg. No. 029436 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,**

		• **Submission of revised formulation and label claim as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 045231997664 dated 23.02.2023. • The firm has not revised the formulation (uncoated to coated).
	Decision: Approved with following label; **Each film coated tablet contains;** **Fexofenadine HCl……..180mg** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
469.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	NILSIT Oral DROPS 100,000IU/ml
	Composition	Each ml Contains; Nystatin ……100,000IU
	Dairy No. date of R &I fee	Dy. No. 15305 dated 07.03.2019. Fee paid vide voucher No. 0835973 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	INTESTINAL ANTIINFECTIVES, Antibiotics. ATC Code: A07AA02
	Type of form	Form-5
	Finished product specifications	
	Pack size and Demand Price	30ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	NYSTATIN ORAL SUSPENSION BP MHRA Approved.
	Me-too-status	Nilstat Drops Reg. No. 001554 M/s ICI Pakistan Hattar.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	It is not mentioned what will be the specifications of Finished Product.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 12683796 dated 23.02.2023. • The firm has stated that specifications of finished product will be of USP.
	Decision: Approved with USP specifications.	
470.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Cream / Ointment Section (General)
	Brand Name + Dosage Form and Strength	NITRA 20mg/g Cream
	Composition	Miconazole Nitrate 2.0 %
	Dairy No. date of R &I fee	Dy. No. 15347 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836440 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIFUNGALS FOR TOPICAL USE, Imidazole and triazole derivatives. ATC Code: D01AC02
	Type of form	Form-5A
	Finished product specifications	BP Specifications
	Pack size and Demand Price	10 gm, 20 gm. As per SRO

	Approval status of product in Reference Regulatory Authorities	Daktarin 2% Cream MHRA Approved
	Me-too-status	Myconit Cream Reg. No. 009936 M/s EPLA Laboratories (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Label claim of tablet is given instead of cream. iii. Strength needs to be correct to %w/w.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of proper label claim, formulation and specifications.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 29543124843 dated 23.02.2023. • The firm has provided the strength as Miconazole nitrate……2.0%. with following claim; Each gram contains; Miconazole nitrate…..20mg • Specifications & formulation are not submitted. • The firm has revised description of product from cream to Nitra 20mg/g Oral gel • The me-too and RRA (Daktarin 2% oral gel MHRA Approved) of revised formulation are available, but the innovator does not use nitrate salt in the gel formulation. (it is used in cream formulation)
	Decision: Approved with BP Specifications and following label; **Each gram contains;** **Miconazole ….20mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
471.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	OPRAM 5.0mg Tablets
	Composition	Each Film Coated Tablet Contains; Escitalopram as Oxalate ….. 5mg
	Dairy No. date of R &I fee	Dy. No. 15267 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829582 dated 07.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	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 5mg Reg. No. 059033 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**

	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 9115034534 dated 23.02.2023.
	Decision: Approved.	
472.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	OPRAM 10mg Tablets
	Composition	Each Film Coated Tablet Contains; Escitalopram as Oxalate ….. 10mg
	Dairy No. date of R &I fee	Dy. No. 15268 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829583 dated 07.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	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	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 43381508276 dated 23.02.2023.
	Decision: Approved.	
473.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	OPRAM 20.0 MG Tablet
	Composition	Each Film Coated Tablet Contains; Escitalopram as Oxalate …… 20 mg
	Dairy No. date of R &I fee	Dy. No. 15266 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829581 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antidepressants, Selective serotonin reuptake inhibitors. ATC Code: N06AB10
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cipralex 20 mg film-coated tablets MHRA Approved
	Me-too-status	Cipralex Fim-Coated Tablets 20 mg Reg. No. 059035 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The strength of tablet at S. No 4 of page 4 is mentioned as 5 mg. This needs to be corrected along

		with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Submission of proper formulation and strength.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 7050573966 dated 23.02.2023. • The firm has submitted corrected formulation and strength.
	Decision: Approved.	
474.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VERINE 135 mg Tablet
	Composition	Each Film Coated Tablet Contains; Mebeverine HCl ……. 135 mg
	Dairy No. date of R &I fee	Dy. No. 15310 dated 07.03.2019. Fee paid vide voucher No. 0835979 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Drugs For Functional Gastrointestinal DisordersSynthetic Anticholinergics, Esters With Tertiary Amino Group ATC Code: A03AA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Mebeverine hydrochloride 135mg Film-coated Tablets PL 21880/0250-252; UK/H/7036-37/001/DC MHRA Approved.
	Me-too-status	Spasfre Tablet 135mg Reg. No. 041750 M/s Himont Pharmaceuticals Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 7245166756 dated 23.02.2023.
	Decision: Approved.	
475.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VERINE 200 mg Tablet
	Composition	Each Fim Coated Tablet Contains; Mebeverine HCl…….. 200 mg
	Dairy No. date of R &I fee	Dy. No. 15322 dated 07.03.2019. Fee paid vide voucher No. 0835991 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Drugs for Functional Gastrointestinal DisordersSynthetic Anticholinergics, Esters with Tertiary Amino Group ATC Code: A03AA04
	Type of form	Form-5-A
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Could not be found. The one provided by the applicant is a modified release capsule of Mebeverine.

	Me-too-status	Mebever MR Capsule 200mg Reg. No. 050747 M/s Getz Pharma
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	ii. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 iii. The firm shall submit Approval status of product in Reference Regulatory Authorities. iv. The firm shall submit evidence of me too of same strength.
	Decision of 323rd RB	Deferred for following; • Submission of correct Form-5 along with full fee. • 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.
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 0259116523 dated 23.02.2023. • The firm has revised the label as under; Each Capsule Contains; Mebeverine hydrochloride prolonged release pellets eq to Mebeverine…….200mg (BP Specifications) Source of pellets: M/s Vision Pharma
	Decision: Approved with Innovator's specifications as per following label claim: Each Capsule Contains; Mebeverine hydrochloride prolonged release pellets eq. to Mebeverine…….200mg	
476.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	VERINE 10mg/ml Oral Solution
	Composition	Given for film coated tablets. (Page 110)
	Dairy No. date of R &I fee	Dy. No. 15311 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835980 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group. ATC Code: A03AA04
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mebeverine hydrochloride 50mg/5ml Oral Suspension MHRA Approved
	Me-too-status	Could not be verified.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Label claim is given for tablet, not for oral liquid. iii. Formulation approved in RRA is a suspension with

		label claim of 50mg/5ml. The applied label claim is different and dosage form is also different (oral solution). Evidence is required for applied formulation in RRA. iv. Evidence of Me-too product is also required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submission of proper formulation, label and specifications of the applied product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 0259116523 dated 23.02.2023. • The firm has revised the label as under; Each 1ml contains; Mebeverine HCl (as Pamoate complex) ….10mg (BP Specifications) • The firm has provided reference of Colofac 10mg/ml Oral Solution and have claimed its approved in ANSM France. The RRA reference is not verifiable. • Me-too of Aspa Suspension 10mg/ml Reg. No. 069474 of M/s Highnoon Labs Lahore is provided. It is verifiable.
	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.	
477.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VISTA 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin as calcium …. 10mg
	Dairy No. date of R &I fee	Dy. No. 15263 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829577 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA07
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rosuvastatin DAWA 5,10, 20 and 40 mg Film-Coated Tablets MHRA Approved.
	Me-too-status	Hyporose 10mg tablet Reg. No. 050414 M/s Mediate Pharmaceutical (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted the correct

		Form-5 along with fee of Rs. 30,000/- vide slip no. 49933732053 dated 23.02.2023.
	Decision: Approved with USP specifications.	
478.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VISTA 20mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin as calcium …. 20mg
	Dairy No. date of R &I fee	Dy. No. 15238 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0758994 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA07
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rosuvastatin DAWA 5,10, 20 and 40 mg Film-Coated Tablets MHRA Approved.
	Me-too-status	Hyporose 20mg tablet Reg. No. 050415 M/s Mediate Pharmaceutical (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 7805789701 dated 23.02.2023.
	Decision: Approved with USP specifications.	
479.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	XAMIC 500mg/5ml Injection
	Composition	Each Injection Contains; Tranexamic Acid…… …. 500 mg
	Dairy No. date of R &I fee	Dy. No. 15285 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0818376 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIHEMORRHAGICS B02A ANTIFIBRINOLYTICS, Amino Acids ATC Code: B02AA02
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2x 10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Cyklokapron Injection, 500mg/5ml Solution for injection MHRA approved.
	Me-too-status	Transamin –INJ Reg. No. 010452 M/s Hilton Pharma (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5

		ii. Route of Administration is mentioned as oral, needs correction. iii. Mention volume of ampouleand also revise label accordingly.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Revision of label as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 381397214274 dated 23.02.2023. • The firm has revised the label as under; Each 5ml Ampoule contains; Tranexamic acid…….500mg (USP Specifications)
	Decision: Approved as per following label claim: **"Each 5ml Ampoule contains:** **Tranexamic acid…….500mg"**	
480.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ZEEN 10mg/ml Injection IV/IM
	Composition	Each 1ml Ampoule Contains; Nalbuphine HCl…….10mg
	Dairy No. date of R &I fee	Dy. No. 15240 dated 07.03.2019. Fee paid vide voucher No. 0758996 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	OPIOIDS, Morphinan derivatives. ATC Code: N02AF02
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified as container and volume is not mentioned.
	Me-too-status	Bunail Injection 10mg/ml Reg. No. 053437 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Dosage Form is mentioned as film coated tablet. iii. Route of Administration is mentioned as oral iv. Evidence of approval of product in RRA could not be verified. Proper Evidence of approval of product having similar volume and container in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **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.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip

		no. 47325806 dated 23.02.2023. • Firm has not provided other details, whether it will be ampoule or vial and what will be the volume of the ampoule or vial.
	Decision: Deferred for submission of details of container closure system and fill volume.	
481.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ZEEN 20mg/ml Injection IV/IM
	Composition	Each 1ml Ampoule Contains; Nalbuphine HCl…….20mg
	Dairy No. date of R &I fee	Dy. No. 15231 dated 07.03.2019. Fee paid vide voucher No. 0758795 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	OPIOIDS, Morphinan derivatives. ATC Code: N02AF02
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified as container and volume is not mentioned.
	Me-too-status	Bunail Injection 20mg/ml Reg. No. 053438 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Dosage Form is mentioned as film coated tablet. iii. Route of Administration is mentioned as oral iv. Evidence of approval of product in RRA could not be verified. Proper Evidence of approval of product having similar volume and container in RRA is required.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **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.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 6610606744 dated 23.02.2023. • Firm has not provided other details, whether it will be ampoule or vial and what will be the volume of the ampoule or vial.
	Decision: Deferred for submission of details of container closure system and fill volume.	
482.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form andStrength	ZINEDAL 5mg/5ml Syrup
	Composition	Each 5 ml contains Cetirizine dihydrochloride ……. 5 mg

	Dairy No. date of R &I fee	Dy. No. 15230 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0758794 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Piperizine derivatives ATC Code: R06AE07
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine Hydrochloride 5 mg/5 ml Oral Solution MHRA Approved.
	Me-too-status	Rigix Oral Solution Reg. No. 020308 M/s AGP (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. In me-too and RRA Cetrizine hydrochloride is approved, not dihydrochloride. Label and formulation shall be corrected along with submission of requisite fee.
	Decision of 323rd RB	**Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Or,** • **Correction for salt of API as per innovator product.**
	Remark of the Evaluator.	• The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 45953592332 dated 23.02.2023. • Firm has revised the label as under; Each 5ml contains; Cetirizine dihydrochloride……5mg (USP Specifications) • Oral syrup approved in RRA contains Cetirizine hydrochloride. Firm still needs to revise the label as per innovator product.
	Decision: Approved with USP Specifications and following label; **Each 5ml contains;** **Cetirizine hydrochloride……5mg** **(USP Specifications)** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
483.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ZINEDAL 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Cetirizine dihydrochloride……5mg
	Dairy No. date of R &I fee	Dy. No. 15229 dated 07.03.2019. Fee paid vide voucher No. 0758793 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives ATC Code: R06AE07
	Type of form	Form-5-A

	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine dihydrochloride 10 mg film-coated tablets (cetirizine dihydrochloride) - PL 20416/0278 MHRA Approved.
	Me-too-status	Rigix 10mg Tablet Reg. No. 011248 M/s AGP Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision of 323rd RB	**Deferred for submission of correct Form-5 along with full fee.**
	Remark of the Evaluator.	The firm vide letter No. nil dated nil has submitted the correct Form-5 along with fee of Rs. 30,000/- vide slip no. 2233915704 dated 23.02.2023.
	Decision: Approved.	
484.	Name and address of manufacturer/ Applicant	M/s Danas Pharmaceuticals, Islamabad
	Brand Name + Dosage Form + Strength	Drotaven Injection
	Composition	Each 2ml ampoule contains: Drotaverine HCl……40mg
	Diary No. Date of R & I & fee	Dy. No.764; 31-05-2017; Rs.20,000/- (30-5-2017)
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	2mlx25's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	No-Spa by Sanofi- Aventis
	GMP status	The firm was granted GMP certificate based on inspection conducted on 03-10-2017.
	Remarks of the Evaluator	Approval in RRA could not be confirmed.
	Decision of 282nd RB meeting:	**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.**
	Remarks of the Evaluator	The firm vide letter No. DP/PEC/2023/001 dated 20.02.2023 has submitted that the product is approved in 3 European countries and has given following references; 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI **Hungary** Approved) (Link: https://www.ogyei.gov.hu/gyogyszeradatbazis/index.php?action=show_details&item=11235) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD **Romania** Approved) (Link: https://www.anm.ro/_/_RCP/RCP_6973_10.10.14.pdf) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, **Bulgaria** Approved) (Link: http://www.bda.bg/images/stories/documents/register/drugs/details/lf2120.htm)

	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.	
485.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Pipral 40mg/320mg Capsule
	Composition	Each capsule contains: Dihydroartemisinin…40mg Piperaquine Phosphate…320mg
	Diary No. Date of R & I & fee	Dy.No 3174 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x8"s,16"s,24"s, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in capsule form.
	Me-too status	070697 Neo Fansidar 40mg/320mg Capsule By M/s Martin Dow
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	Evidence of approval of applied formulation in capsule form. in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision of 295thRB meeting:	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted that they are applying for new revised formulation/composition as below; Each film coated tablet contains; Dihydroartemisinin……..40mg Piperaquine as phosphate….320mg • For RRA: Dihydroartemisinin/Piperaquine (phosphate) 40mg / 320mg film-coated tablets WHO approved formulation • For me-too: Peproxin Tablets 40mg /320mg by M/s Wnsfield Pharmaceuticals (Reg#084229) • The firm has not submitted any fee for the changes.
	Decision: Approved as per following label claim: **Each film coated tablet contains;** **Dihydroartemisinin……..40mg** **Piperaquine as phosphate….320mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
486.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Roxen 12.5mg Tablets
	Composition	Each film coated tablet contains: Paroxetine …12.5mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 13502 dated 11-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors

	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10‘s, 20‘s, 30‘s / As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR Controlled-Release 12.5mg Tablets by M/s GlaxoSmithKline (USFDA Approved)
	Me-too status	Panox CR 12.5mg Tablet of Regal Pharma (Reg. #081953)
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	Master formulation not submitted by the firm. Firm has applied as film coated tablet whereas approved formulation in USFDA is enteric coated controlled-release tablet Firm has applied as Paroxetine …12.5mg whereas USFDA approved formulation is Paroxetine (as hydrochloride) …12.5mg
	Decision of 295thRB meeting:	**Deferred for revision of formulation along with submission of requisite fee.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted that they are applying for new revised formulation as below; Each enteric, film coated controlled-release tablet contains; Paroxetine (as Hydrochloride) …….12.5mg • Fee is not submitted.
	Decision: Approved as per following label claim: **Each enteric, film coated controlled-release tablet contains;** **Paroxetine (as Hydrochloride) ……. 12.5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
487.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	K-Tan 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…25mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 13502 dated 11-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10‟s,20‟s,30‟s,As per SRO.
	Approval status of product in Reference Regulatory Authorities	COZAAR® (losartan potassium) tablets Approved in USFDA with box warning.
	Me-too status	076112 Losaan 25mg Tablet M/s Maple Karachi . .
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	Application is not as per prescribed form only checklist is provided with annexures.
	Decision of 295thRB meeting:	**Deferred for submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted filled and signed Form-5.
	Decision: Approved.	

488.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	K-Tan 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg
	Diary No. Date of R & I & fee	Dy.No 2061 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10"s,20"s,30"s,As per SRO.
	Approval status of product in Reference Regulatory Authorities	COZAAR® (losartan potassium) tablets Approved in USFDA with box warning.
	Me-too status	057848 Losanta 50mg Tablet M/s Asian Continental (Pvt.) Ltd Karachi
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	Application is not as per prescribed form only checklist is provided with annexures.
	Decision of 295thRB meeting:	**Deferred for submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted filled and signed Form-5.
	Decision: Approved.	
489.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	K-Tan 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…100mg
	Diary No. Date of R & I & fee	Dy.No 2062 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10"s,20"s,30"s,As per SRO.
	Approval status of product in Reference Regulatory Authorities	COZAAR® (losartan potassium) tablets Approved in USFDA with box warning.
	Me-too status	079743 "Xavor Tablet M/s Ferozesons Labs,P.O Ferozesons Amangarh, Nowshera."
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	Application is not as per prescribed form only checklist is provided with annexures.
	Decision of 295thRB meeting:	**Deferred for submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted filled and signed Form-5.
	Decision: Approved.	

490.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Bactalid Suspension 100mg/5ml
	Composition	Each 5ml contains: Linezolid…100mg
	Diary No. Date of R & I & fee	Dy.No 775 dated 07-01-2019 Rs.20,000/- Dated 03-01-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60ml,90ml,120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZYVOX® (linezolid) injection, tablets and oral suspension USFDA approved.
	Me-too status	081983 Linzol 100mg /5ml oral dry suspension M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad . .
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	• Justification for the qty of linezolid i.e 1.2 g per bottle mentioned in master formulation. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision of 295thRB meeting:	**Deferred for scientific Justification for using overage.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted that quantity of 1.2gm per bottle was written for the 60ml pack size against the label claim of 100mg per 5ml. This was not an overage.
	Decision: Approved.	
491.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Laxit 3.35g/5ml Syrup
	Composition	Each 5ml Contains: Lactulose…3.35g
	Diary No. Date of R & I & fee	Dy.No 768 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Osmotically acting laxatives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml,90ml,120ml,As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Lactusure Syrup of Medisure Laboratories Pakistan
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Lactulose solution is present in USP you have applied for syrup.

		• Submission of details regarding source of Lactulose, GMP certificate of manufacturer, stability studies of 03 batches conducted under the conditions of Zone IV-A and if Lactulose is imported then the fee Rs. 100,000/- should be submitted.
	Decision of 295thRB meeting:	**Deferred for submission of COA, GMP of lactulose manufacturer and stability studies of three batches of lactulose conducted in accordance with zone IV-A conditions. & differential fee of Rupee 80,000/- in case of imported lactulose.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted that they will use the previously approved source of M/s Fresenius Kabi Austria GmbH Registration board meeting -321. • Fee has not been paid.
	Decision: Approved **The firm shall submit fee of Rs. 80,000/- for imported source of bulk solution as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
492.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Obsonil 120mg Capsule
	Composition	Each Capsule Contains: Orlistat…120mg
	Diary No. Date of R & I & fee	Dy.No 3173 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Peripherally acting anti-obesity products
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10"s,2x10"s, 3x10"s, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved .
	Me-too status	068689 Orly Capsules 120 mg M/s Rotex Medica Pakistan (Pvt) Ltd., P.No. 206-207, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	• The applied formulation is present in the form of pellets whereas, you have not applied for pellets. • Submission of source of pellets, GMP of manufacturer of pellets, Certificate of analysis of pellets, Real time and accelerated stability study data of 3 batches, conducted according to the requirements of zone IV-A, Differential fee (if the pellets are imported). *Deferred in previous meetings for further deliberation upon requirement of accelerated stability studies data of Orlistat IR pellets*.
	Decision of 295thRB meeting:	**Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has submitted that they will use the previously approved source of M/s Vision Pharmaceuticals. Registration board meeting -321.

		• Other details are not provided. Fee for variation is also not submitted.
	Decision: Deferred for submission of stability data requirement for Orlistat 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.	
493.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Azimed 200mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Azithromycin…200mg
	Diary No. Date of R & I & fee	Dy.No.43948 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Anti- infective
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10"s,2x10"s, 3x10"s, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved .
	Me-too status	Azithrolide Dry Powder Suspension M/s Heal Pharma, Peshawar (Registration No.084236)
	GMP status	28-09-2017 and good
	Remarks of the Evaluator	• Azithromycin "as monohydrate" is approved in MHRA. • Manufacturing facility / section needs to be confirmed.
	Decision of 295thRB meeting:	**Deferred for evidence of approval of relevant/required manufacturing facility and revision of formulation as per the innovator / reference product along with submission of fee for revision of formulation.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has applied for revised composition as under; Each 5ml contains; Azithromycin as monohydrate…..200mg • Renewal letter dated 14.02.2020 is submitted wherein Dry Powder Suspension section is mentioned. • Fee for variation is not submitted.
	Decision: Approved as per following label claim: **Each 5ml of reconstituted suspension contains;** **Azithromycin as monohydrate…..200mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
494.	Name and address of manufacturer/ Applicant	**M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi**
	Brand Name + Dosage Form + Strength	Esfen 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Flurbiprofen…100mg
	Diary No. Date of R & I & fee	Dy.No 765 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10"s,20"s,30"s, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed as film coated tablets.

	Me-too status	058160; Fenbiflor 100mg Tablet M/s Lisko Pakistan Ltd, Karachi
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator	Evidence international availability as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision of 295thRB meeting:	**Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet along with submission of requisite fee, master formulation & manufacturing method.**
	Remarks of the Evaluator	• The firm vide letter No. Nil dated nil has stated that film coated tablet previously approved in registration board meeting -320 M/s Islam Pharmaceuticals 7-KM Pasrur Road Sialkot. • The reference of applied formulation has been verified from Health Canada.
	Decision: Approved	
495.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad Contract manufactured by Bio labs Pharmaceuticals., plot No. 145 Industrial triangle Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	S-Zole Injection 40mg
	Composition	Each vial contains omeprazole (as sodium)……..40mg
	Diary No. Date of R & I & fee	Dy No.1486; 09-03-2015; Rs. 20000/-
	Pharmacological Group	Poton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	1's vial; As per PRC.
	Approval status of product in Reference Regulatory Authorities	MHRA approved.
	Me-too status	Loprot injection 40mg by Nabiqasim
	GMP status	The firm was granted GMP certificate based on inspection conducted on 05 & 06-12-2017.
	Remarks of the Evaluator	Firm has claimed Innovator specs and applied formulation does not exist in Available USP and B.P.
	Decision of 278thRB meeting:	Deferred for clarification of submitted manufacturing method for applied formulation. (M-278)
	Remarks of the Evaluator	The firm has provided Lyophilized vials (General). The firm has submitted detailed method of manufacturing with following steps: ● Stage 1-De-cartoning & Vial washing ● Stage 2-Dry Heat sterilization ● A- Autoclaving ● Stage 3-Freeze Drying or lyophilisation ● Stage 4-Packaging
	Decision of 282ndRB meeting:	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/186/02/23 dated 22.02.2023 has submitted capacity assessment report of M/s

		Bio labs Pvt. Ltd. The inspection was conducted on 12.12.2019. It was placed in 293rd meeting of RB. the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: i. Dry Suspension (Cephalosporin) ii. Capsule (Cephalosporin) iii. Dry vial injectable (Cephalosporin) iv. lyophilized vial injectable (General)
	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.	
496.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad Contract manufactured by Bio labs Pharmaceuticals., plot No. 145 Industrial triangle Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	S-Eso Injection 40mg
	Composition	Each vial contains Esomeprazole (as sodium)……..40mg
	Diary No. Date of R & I & fee	Dy No.1488; 09-03-2015; Rs. 20000/-
	Pharmacological Group	Poton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	1's vial; As per PRC.
	Approval status of product in Reference Regulatory Authorities	MHRA approved.
	Me-too status	Esopep by Global Pharmaceuticals.
	GMP status	The firm was granted GMP certificate based on inspection conducted on 05 & 06-12-2017.
	Remarks of the Evaluator	Firm has claimed Innovator specs and applied formulation does not exist in Available USP and B.P.
	Decision of 278thRB meeting:	Deferred for clarification of submitted manufacturing method for applied formulation. (M-278)
	Remarks of the Evaluator	The firm has provided Lyophilized vials (General). The firm has submitted detailed method of manufacturing with following steps: ● Stage 1-De-cartoning & Vial washing ● Stage 2-Dry Heat sterilization ● A- Autoclaving ● Stage 3-Freeze Drying or lyophilisation ● Stage 4-Packaging
	Decision of 282ndRB meeting:	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/186/02/23 dated 22.02.2023 has submitted capacity assessment report of M/s Bio labs Pvt. Ltd. The inspection was conducted on 12.12.2019. It was placed in 293rd meeting of RB. the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: i. Dry Suspension (Cephalosporin) ii. Capsule (Cephalosporin) iii. Dry vial injectable (Cephalosporin) iv. lyophilized vial injectable (General)

	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.	
497.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad Contract manufactured by Bio labs Pharmaceuticals., plot No. 145 Industrial triangle Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Pantozole Injection 40mg
	Composition	Each vial contains: Pantoprazole (as sodium sesquihydrate) lyophilized powder……40mg
	Diary No. Date of R & I & fee	Dy No.1487; 09-03-2015; Rs. 20000/-
	Pharmacological Group	Poton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	1's vial; As per PRC.
	Approval status of product in Reference Regulatory Authorities	MHRA approved.
	Me-too status	Lesprot of Nabiqasim Industries
	GMP status	The firm was granted GMP certificate based on inspection conducted on 05 & 06-12-2017.
	Remarks of the Evaluator	Firm has claimed Innovator specs and applied formulation does not exist in Available USP and B.P.
	Decision of 278thRB meeting:	Deferred for clarification of submitted manufacturing method for applied formulation. (M-278)
	Remarks of the Evaluator	The firm has provided Lyophilized vials (General). The firm has submitted detailed method of manufacturing with following steps: ● Stage 1-De-cartoning & Vial washing ● Stage 2-Dry Heat sterilization ● A- Autoclaving ● Stage 3-Freeze Drying or lyophilisation ● Stage 4-Packaging
	Decision of 282ndRB meeting:	**Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.**
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/186/02/23 dated 22.02.2023 has submitted capacity assessment report of M/s Bio labs Pvt. Ltd. The inspection was conducted on 12.12.2019. It was placed in 293rdmeeting of RB. the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: i. Dry Suspension (Cephalosporin) ii. Capsule (Cephalosporin) iii. Dry vial injectable (Cephalosporin) iv. lyophilized vial injectable (General)
	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.	
498.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Axoff 40mg tablet
	Composition	Each film coated tablet contains:

		Febuxostat…….40mg
	Diary No. Date of R & I & fee	Dy.2685; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Anti-Gout
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Febuxin by M/s AGP, Karachi (Reg. No. 081104)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	No official monograph is available for applied formulation in USP or BP.
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the i. shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	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.	
499.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Axoff 80mg tablet
	Composition	Each film coated tablet contains: Febuxostat…….80mg
	Diary No. Date of R & I & fee	Dy.2690; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Anti-Gout
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Febuxin by M/s AGP, Karachi (Reg. No. 081104)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	No official monograph is available for applied formulation in USP or BP.
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the

		ii. shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	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.	
500.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Paradol tablets
	Composition	Each film coated tablet contains: Paracetamol……..325mg Tramadol hydrochloride……37.5mg
	Diary No. Date of R & I & fee	Dy. No 2691; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Analgesic/ Opioid Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ultracet by Janssen (USFDA)
	Me-too status	Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	Decision: Approved.	
501.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad.

	Brand Name + Dosage Form + Strength	Levictam 500mg tablet
	Composition	Each film coated tablets Contains: Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Dy. No 2687; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Second generation antiepileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Keppra Tablets 500mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045685)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	Decision: Approved.	
502.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Levictam 250mg tablet
	Composition	Each film coated tablets Contains: Levetiracetam…….250mg
	Diary No. Date of R & I & fee	Dy. No 2689; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Second generation antiepileptic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Keppra Tablets 250mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045684)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP

		guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	Decision: Approved.	
503.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Vamlodip-DS tablets
	Composition	Each film coated tablets Contains: Amlodipine as besylate……10mg Valsartan……..160mg
	Diary No. Date of R & I & fee	Dy. 2686; 15-06-2016; Rs.20,000/- (15-06-2016)
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Valpine Tablets 10/160mg by M/s Fassgen Pharmaceuticals, (Reg. No. 073303)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	Decision: Approved.	
504.	Name and address of manufacturer/ Applicant	M/s Sawan pharmaceuticals 11-E Industrial triangle Kahuta Road, Islamabad

	Brand Name + Dosage Form + Strength	Sertowan 50 mg tablet
	Composition	Each film coated tablets Contains: Sertraline (as hydrochloride) …… 50mg
	Diary No. Date of R & I & fee	Dy. No 2688; 15-06-2016; Rs.20,000/- (15-06-2016)
	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	Approved by MHRA of UK
	Me-too status	Ertalin 50 mg Tablets of M/s Genome Pharma, (Reg.#076844)
	GMP status	Last inspection conducted on 21-12-2016.
	Remarks of the Evaluator	
	Decision of 275thRB meeting:	Deferred for updated status of GMP from QA&LT Division **(M-275)**.
	Remarks of the Evaluator	GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report.
	Decision of 288thRB meeting:	Deferred for updated status of GMP of the firm form QA & LT division as inspectionreport submitted by firm does not conclude GMP compliant status.
	Remarks of the Evaluator	The firm vide letter No. Sw/Reg/188/03/23 dated 30.03.2023 has submitted copy of DML renewal report. The inspection was conducted on 13.12.2022. The panel has recommended renewal of following sections; • Tablet (general) • Capsule(general) • Liquid Ampoule (general) • Injection (psychotropic)
	Decision: Approved.	

Agenda of Evaluator PEC-X

Case no. 01 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

507.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Amoxy Add Water Soluble Powder
	Composition	Each Kg contains: Amoxicillin Trihydrate…50gm Lysozyme Chloride…10gm Guaifenesin…35gm
	Diary No. Date of R& I & fee	Dy.No 12320 dated 06-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form 5
	Finished product Specification	**Not mentioned**
	Pack size & Demanded Price	**Not mentioned**; Decontrolled
	Me-too status	Amoxy Add Water Soluble Powder of M/s Samyang Anipharm Co., Seoul, Korea (Reg. No. 069649)

	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator X	**Oral powder (Penicillin) Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018. **Shortcomings:** • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide Master formulation describing quantities of actives and excipients alongwith their justification/role of ingredients. • Provide outline of method of manufacturing. • "Pack size" is not mentioned in form-5.
	Decision: Deferred for following: • **rationality and solubility of formulation** • **finished product specifications in the light of decision taken in 267th meeting of Registration Board.** • **master formulation describing quantities of actives and excipients alongwith their justification/role of ingredients.** • **outline of method of manufacturing.** • **demanded pack size**	
508.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ras Fosfocin Oral Powder
	Composition	Each 100gm Contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 17574 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10gm, 15gm, 25gm, 50gm, 100gm, 220gm, 500gm,1Kg
	Me-too status	Fosomax Oral Powder of M/s Biogen Pharma, Rawat (Reg. No. 063808)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator X	• **Oral Powder (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. Each 100gm Contains: Fosfomycin Calcium…20gm Tylosin as Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm **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, along with latest GMP inspection report conducted within the period of last three years before issuance of registration letter.**	

509.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Floraxin Oral Powder
	Composition	Each 100gm Contains: Oxytetracycline HCl…30gm Neomycin Sulphate…15gm Florfenicol…10gm
	Diary No. Date of R& I & fee	Dy.No 17579 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm,1Kg, 5Kg, 25Kg; N/A
	Me-too status	Stenop Powder of M/s Majestic Pharma, Faisalabad. (Reg. No. 089846)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator X	• **Oral Powder (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
510.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tylo-G Injection 50ml
	Composition	Each ml Contains: Gentamicin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy.No 17796 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Tylogent Injection (50ml) of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator X	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020. or Gentamicin Sulphate…50mg Tylosin Tartrate…100mg/ml however, the reference formulation is **Each ml Contains:** **Gentamicin as Sulphate…50mg** **Tylosin as Tartrate…100mg** • Firm shall submit fee of Rs.30000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml Contains:** **Gentamicin as Sulphate…50mg** **Tylosin as Tartrate…100mg**	

	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.	
511.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Floxa-10 Injection 50ml
	Composition	Each ml Contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 17795 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Enflox-10% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112212)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator X	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
512.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tylomore-50% WSP
	Composition	Each Kg contains: Tylosin Tartrate…500gm
	Diary No. Date of R& I & fee	Dy. No 17588 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,500gm,1000gm: Decontrolled
	Me-too status	Tyrate Powder of M/s Farm Aid Group, Haripur (Reg. No. 099054)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Dry Powder Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML.
	Decision: Approved. **Each 100g contains:** **Tylosin as Tartrate…50gm** **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, along with latest GMP inspection report conducted within the period of last three years before issuance of registration letter.**	
513.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Enro More-C WSP
	Composition	Each 100gm Contains: Enrofloxacin…20gm Colistin Sulphate…45 MIU
	Diary No. Date of R& I & fee	Dy.No 17596 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,500gm,1000gm: Decontrolled

	Me-too status	Encowim Powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 099288)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**der Section (General)** confirmed vide panel inspection report renewal of DML. f Colistin Sulphate from MIU to grams. (1MIU= 0.05236)
	Decision: Approved. 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.	
514.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Moryso WSP
	Composition	Each gram contains: **Lysozyme**…22% Vitamin E 50…0.5%
	Diary No. Date of R& I & fee	Dy.No 17585 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	**Antibiotic combination**
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,500gm,1000gm: Decontrolled
	Me-too status	Apla-Zee Oral Powder of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 097887)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**der Section (General)** confirmed vide panel inspection report renewal of DML. p mentioned in the form-5 is not correct. The firm shall submit correction/pre-approval change in product specifications and p as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-
	Decision: Referred to expert working group for rationality and solubility of applied formulation.	
515.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Enramore Oral WSP
	Composition	Each Kg contains: Enramycin…80gm
	Diary No. Date of R& I & fee	Dy.No 17583 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm,1000gm: Decontrolled
	Me-too status	Eladine Powder of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 101453)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**der Section (General)** confirmed vide panel inspection report renewal of DML
	Decision: Approved.	

	Each 100g contains: Enramycin…8gm **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.**	
516.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	PSB More-N WSP
	Composition	Each Kg contains: **Procaine Penicillin**…12gm **Streptomycin Sulphate**…36gm **Neomycin Sulphate**…10gm **Zinc Bacitracin**…52gm
	Diary No. Date of R& I & fee	Dy.No 17587 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	Biocillin SN Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 097941)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Shortcomings:** **ry Dry Powder (Penicillin)** section/manufacturing facility by Board. However, you may submit panel inspection report for ying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
517.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	PSB Plus WSP
	Composition	Each Kg Contains: **Procaine Penicillin…12gm** **Streptomycin…36gm** **Colistin Sulphate…60 MIU** **Zinc Bacitracin…52gm**
	Diary No. Date of R& I & fee	Dy.No 17584 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	C-ZPS 100/60 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113454)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Shortcomings:** **ry Dry Powder (Penicillin)** section/manufacturing facility by Board. However, you may submit panel inspection report for ying the section/manufacturing facility. Colistin Sulphate from MIU to grams. or Procaine Penicillin…12gm, **Streptomycin…36gm,** Colistin U and Zinc Bacitracin…52gm per Kg, while the referred generic **Each Kg contains:**

		Procaine Penicillin…12gm **Streptomycin sulphate…36gm** **Colistin Sulphate…60,00000 IU** **Zinc Bacitracin…52gm**
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
518.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Doximore 50% Oral WSP
	Composition	Each 100gm contains: Doxycycline…50gm
	Diary No. Date of R& I & fee	Dy.No 17580 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm,1000gm: Decontrolled
	Me-too status	Aerodox-50 Oral Water Soluble Powder of M/s Sanna Laboratories, Faisalabad (Reg. No. 101486)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Dry Powder Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML **Shortcomings:** rm is required.
	Decision: Deferred for submission of following: • **Clarification of salt form** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
519.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Moreno Mox C WSP
	Composition	Each gram contains: Amoxicillin Trihydrate…200mg Colistin Sulphate…60,00,000 IU
	Diary No. Date of R& I & fee	Dy.No 17582 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	Cola-Moxin 200 Water Soluble Powder of M/s Inshal Pharmaceutical Industries, Islamabad (Reg. No. 099339)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	Provided conversion of Colistin Sulphate from MIU to grams. (1MIU=0.05236gm) **Shortcomings:** anufacturing facility by the Central Licensing Board. However, nel inspection report for renewal of DML verifying the facility.
	Decision: Deferred for confirmation of Veterinary Dry Powder Section (Penicillin) by the Central Licensing Board.	
520.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.

	Brand Name +Dosage Form + Strength	Floramore-C Oral Liquid
	Composition	Each ml Contains: Florfenicol…230gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 17581 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Nobifen-C 23% Oral Liquid of M/s Noble Pharma, Mirpur Azad Kashmir. (Reg. No. 099052)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML • Provided conversion of Colistin Sulphate from MIU to grams. (1MIU=0.05236gm)
	Decision: Approved.	
521.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Floramore-23% Oral Liquid
	Composition	Each 100ml contains: Florfenicol…23gm
	Diary No. Date of R& I & fee	Dy.No 17593 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Fenster-23 Oral Liquid of M/s Aamster Laboratories, Islamabad. (Reg. No. 099480)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Approved.	
522.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Dia Zine-T Oral Suspension
	Composition	Each ml contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 17595 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Evoprim Oral Suspension of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 099062)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.

	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML.
	Decision: Approved.	
523.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Bromothol Oral Solution
	Composition	Each ml contains: Bromhexine HCl…50mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 17586 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	**Antibacterial**
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Manster B 90 Oral Liquid of M/s Aamster Laboratories, Rawat, Islamabad (Reg. No. 101499)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML **Shortcomings:** p mentioned in the form-5 is not correct. The firm shall submit orrection/pre-approval change in pharmacological group as per /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 before issuance of registration letter.	
524.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tilcomore Oral Solution
	Composition	Each ml Contains: Tilmicosin Phosphate…250mg
	Diary No. Date of R& I & fee	Dy.No 17597 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Pritil 2.5% Oral Liquid of M/s Prix Pharmaceutica, Lahore. (Reg. No. 101475)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Approved. **Each ml Contains:** **Tilmicosin as Phosphate…250mg** **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.**	
525.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Enra More-20 Oral Liquid
	Composition	Each 100ml Contains:

		Enrofloxacin…20gm
	Diary No. Date of R& I & fee	Dy.No 17591 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Enster 20 Oral Liquid of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 101501)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Approved.	
526.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Enro More Plus Oral Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxy pyridazine**…75mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 17592 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Marko-Cena Forte Oral Liquid of M/s Vetec Laboratories, Rawat, Rawalpindi (Reg. No. 101493)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
527.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Hexa Morin Oral Liquid
	Composition	Each ml Contains: Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 17594 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	**Antibacterial**
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Cofster-10 Oral Liquid of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No. 101495)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.

	Remarks of the Evaluator X	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML **Shortcomings:** ɒ mentioned in the form-5 is not correct. The firm shall submit orrection/pre-approval change in pharmacological group as per /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 before issuance of registration letter.	
528.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Moreno Mox-50% WSP
	Composition	Each 100gm contains: Amoxicillin Trihydrate…50gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 17589 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	Cola-Moxin 50% Water Soluble Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 099340)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	Provided conversion of Colistin Sulphate from MIU to grams. (1MIU=0.05236gm) **Shortcomings:** **ry Dry Powder (Penicillin)** section/manufacturing facility by Board. However, you may submit panel inspection report for ying the section/manufacturing facility.
	Decision: Deferred for confirmation of approval of Veterinary Dry Powder (Penicillin) section.	
529.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Moreno Mox-80% WSP
	Composition	Each 100gm contains: Amoxicillin Trihydrate…80gm
	Diary No. Date of R& I & fee	Dy.No 17590 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	I-Amamox 80gm Powder of M/s International Pharma Labs., Lahore. (Reg. No. 097993)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator X	**Shortcomings:** **ry Dry Powder (Penicillin)** section/manufacturing facility by Board. However, you may submit panel inspection report for ying the section/manufacturing facility.
	Decision: Deferred for confirmation of approval of Veterinary Dry Powder (Penicillin) section.	

530.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Diaban Oral Liquid
	Composition	Each ml contains: **Sulphadimidine**…35mg **Sulphadiazine**…36mg **Streptomycin Sulphate**…7.6mg **Neomycin Sulphate**…1.8mg Sodium Chloride…11.33mg Calcium Gluconate…2.2mg Magnesium Sulphate…0.6mg Potassium Chloride…3.6mg Kaolin…103.33mg Pectin…7.1mg Glycine…20.9mg
	Diary No. Date of R& I & fee	Dy.No 16154 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial with minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 500ml,1000ml: Decontrolled
	Me-too status	No-Scour Oral Suspension of M/s Nawan Laboratories (Pvt) Ltd., Karachi (Reg. No. 072673)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Liquid (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to expert working group for the suitability of formulation. 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.	
531.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Genta-St Injection 100ml
	Composition	Each ml Contains: Gentamicin as Sulphate…30mg Trimethoprim…25mg Sulphadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 16153 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Genta Plus Injection (100ml) of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031472)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
532.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.

	Brand Name +Dosage Form + Strength	Genta-St Injection 50ml
	Composition	Each ml contains: Gentamicin as Sulphate…30mg Trimethoprim…25mg Sulphadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 16147 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Genta Plus Injection (50ml) of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031472)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
533.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Fosfovet Oral Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm
	Diary No. Date of R& I & fee	Dy.No 16150 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Fosomax Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat. (Reg. No. 063808)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved with following label claim: **Each 100gm contains:** **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…10gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Phosphate…10gm** **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.**	
534.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.

	Brand Name +Dosage Form + Strength	Florcyclin-N Oral Powder
	Composition	Each gm contains: Oxytetracycline HCl…300mg Florfenicol…100mg Neomycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 16151 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Noxyflor Water Soluble Powder of M/s Divine Pharmaceuticals, Lahore. (Reg. No. 087584)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
535.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobipara-C Oral Powder
	Composition	Each 100gm Contains: **Paracetamol**…2gm Vitamin C…20gm Calcium Carbonate…4.5gm Potassium Chloride…4gm Magnesium Sulphate…3.5gm
	Diary No. Date of R& I & fee	Dy.No 15545 dated 01-07-2020 Rs.20,000/- dated 30-06-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm,250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Paralite-C Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 079518)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
536.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Rescosin AC Oral Solution
	Composition	Each ml Contains: Tilmicosin Phosphate…250mg

	Diary No. Date of R& I & fee	Dy.No 15920 dated 03-07-2020 Rs.20,000/- dated 02-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml and 1000ml; Decontrolled
	Me-too status	Motil Liquid of M/s Eterna Pharma (Pvt.) Ltd., Mirpur, AJK. (Reg. No. 113537)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Veterinary Oral Liquid (General)** section granted vide letter No. F.1-41/2007-Lic dated 06-04-2015 • The firm has submitted revised Form-5 along with fee Rs. 30,000/- dated 07-03-2023 vide slip No. 80473252527 for change of title.
	Decision: Approved. **Each ml Contains:** **Tilmicosin as Phosphate…250mg** **The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval for change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
537.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Intergest Water Soluble Powder
	Composition	Each 1000gm contains: Calcium Propionate…201gm Sodium Propionate…402.7gm Magnesium Sulphate...124gm Iron Sulphate...0.41gm Sodium Chloride...264.3gm Vitamin A.....750,000 IU Vitamin D3...350,000 IU Zinc Sulphate...0.11gm Maganese Sulphate...0.21gm Copper Sulphate...0.45gm Cobalt Chloride...0.41gm Sodium Selenite...0.11gm Di Calcium Phosphate...3000mg Vitamin E...1000mg
	Diary No. Date of R& I & fee	Dy.No 17167 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Mineral supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings:** • Evidence of testing facility • 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 testing facility** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

538.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Oxyline Plus 5% Injection
	Composition	Each ml contains: Oxytetracycline HCl…50mg Lignocaine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 17166 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Antibiotic/Local anaesthetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Oxyjet-50 Injection (100ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 111562)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved. 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.	
539.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Antizine Injectable Powder
	Composition	Each vial contains: Diminazine Aceturate…1.05gm Antipyrine…1.31gm
	Diary No. Date of R& I & fee	Dy.No 17172 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2.36gm vials: Decontrolled
	Me-too status	Tryptowan Injection of M/s Nawan Laboratories (Pvt) Ltd, Karachi (Reg. No. 025761)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for review by expert working group for veterinary drugs.	
540.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Veta-D3 Injection
	Composition	Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 17163 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled

	Me-too status	VAD3 Injection (100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059179)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019. • Provided conversion of vitamin A and vitamin D3 from IU to milligrams. (80,000 IU = 160mg 40,000 IU = 80mg)
	Decision: Approved. 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.	
541.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Intermectin 2% Injection
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 17165 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Selmec Injection (50ml) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071087)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved. 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.	
542.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Lincospect Injection 50ml
	Composition	Each ml contains: Lincomycin as HCl…50mg Spectinomycin…100mg
	Diary No. Date of R& I & fee	Dy.No 17171 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Linco-S Injection (50ml) of M/s Jfrin Pharmaceuticals, Karachi (Reg. No. 043248)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved. 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.	

543.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Iver-C Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 17168 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Actimec Plus Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved. 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.	
544.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Intervac-B12 Injection
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 17169 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml Vial: Decontrolled
	Me-too status	Cynosel Forte 1000mcg Injection (100ml) Of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 112276)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	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.	
545.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Sulfa-L Bolus
	Composition	Each Bolus Contains: Sulphadimidine…350mg
	Diary No. Date of R& I & fee	Dy.No 17170 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50s: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.

	Remarks of the Evaluator [X]	• **Bolus section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **Shortcomings**: • Clarification of salt form • 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: • **Clarification of salt form** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
546.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Niclofas Bolus
	Composition	Each Bolus Contains: Niclosamide…1250mg
	Diary No. Date of R& I & fee	Dy. No 17164 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50s: Decontrolled
	Me-too status	Niclozak Bolus of M/s Zakfas Pharmaceuticals Pvt Ltd., Multan. (Reg. No.112310)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Bolus section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019
	Decision: Approved. 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.	
547.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Lysoras Oral Powder
	Composition	Each Gram Contains: **Lysozyme**…22% Vitamin E 50%...0.5%
	Diary No. Date of R& I & fee	Dy.No 17578 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Enzyme/Vitamin
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm,1Kg, 5Kg, 25Kg; N/A
	Me-too status	Vitozyme Powder of M/s Selmore Pharmaceuticals (Pvt.) Ltd., Lahore. (Reg. No. 049622)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	**al) Vet section** confirmed vide panel inspection report based on -2021 for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Deferred for submission of following: • **rationality and solubility of formulation** • **Latest GMP inspection report conducted within the period of last three years.**	

548.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Fosfotic Oral Powder
	Composition	Each 100gm Contains: Calcium Fosfomycin…20gm Tylosin Tartrate…5gm Fructose 1,6 Diphosphate…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm Sodium Chloride…100gm
	Diary No. Date of R& I & fee	Dy.No 17577 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10gm, 25gm, 50gm, 100gm, 250gm, 500gm,1Kg, 5Kg, 25Kg; N/A
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi (Reg. No. 075626)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	**al) Vet section** confirmed vide panel inspection report based on -2021 for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Decision: Approved with following label claim: **Each 100gm contains:** **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…5gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Phosphate…10gm** **Sodium Chloride…100gm** **Moreover, firm shall submit the following before issuance of registration letter** • **Fee of Rs. 30,000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Latest GMP inspection report conducted within the period of last three years.**	
549.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Rasnor-200 Oral Liquid
	Composition	Each 100ml Contains: Norfloxacin HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 17576 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml,1L, 5L, 25L; N/A
	Me-too status	Nor-Oxime Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 080137)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet section** confirmed vide

		panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Deferred for review by expert working group for veterinary drugs.	
550.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Norflox-250 Oral Liquid
	Composition	Each 100ml contains: Norfloxacin HCl…25gm
	Diary No. Date of R& I & fee	Dy.No 17575 dated 20-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml,1L, 5L, 25L; N/A
	Me-too status	Normak Liquid of M/s A & K Pharmaceutical Faisalabad (Reg. No. 058943)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	**al) Vet section** confirmed vide panel inspection report based on -2021 for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Deferred for review by expert working group for veterinary drugs.	
551.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lincoson Powder
	Composition	Each gm contains: Lincomycin HCl…100mg Colistin Sulphate…800,000 IU
	Diary No. Date of R& I & fee	Dy.No 17728 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Colimycin Water Soluble Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 058902)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of f Colistin Sulphate from IU to milligrams. (1mg of Colistin sulphate is equivalent to 19000IU)
	Decision: Approved. **Each gm contains:** **Lincomycin as HCl…100mg** **Colistin Sulphate…800,000 IU** **The firm shall submit the 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.**	
552.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Fenix W/S Powder
	Composition	Each gm contains: Oxytetracycline HCl…150mg Florfenicol…150mg
	Diary No. Date of R& I & fee	Dy.No 17732 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Oxy-Floro Water Soluble Powder of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080726)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
553.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Furaster W/S Powder
	Composition	Each 1000gm Powder Contains: Furosemide…20gm Manganese Sulphate…1gm Potassium Chloride…4gm Calcium Carbonate…45gm Magnesium Sulphate…35gm Sodium Chloride…35gm
	Diary No. Date of R& I & fee	Dy.No 17723 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Diuretic, Electrolyte supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	F-Maars Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad. (Reg. No. 078265)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**ction-I and Oral Powder Section-II (Veterinary)** confirmed report based on inspection conducted on 05-09-2019 for grant
	Decision: Approved. The firm shall submit the Fee of Rs. 30,000/- for correction in formulation (salt form of furosemide), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
554.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lorfen W/S Powder
	Composition	Each 100gm contains: Florfenicol…15gm Neomycin Sulphate…15gm

	Diary No. Date of R& I & fee	Dy.No 17731 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Neo Flor Water Soluble Powder of M/s Farm Aid Group, Estate, Haripur. (Reg. No. 087961)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
555.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fomyster W/S Powder
	Composition	Each 100gm Powder Contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 17730 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial, Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078240)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved with following label claim: **Each 100gm contains:** **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…10gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Sulphate…10gm** **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.**	
556.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ami-Zine Powder
	Composition	Each gm Contains: Piperazine Citrate…1000mg
	Diary No. Date of R& I & fee	Dy.No 17729 dated 21-07-2020 Rs.20,000/- dated 20-07-2020

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Piperapure-1000 Water Soluble Powder of M/s Attabak Pharmaceutical Industries, Islamabad. (Reg. No. 034530)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
557.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Icon Powder
	Composition	Each Kg Contains: Lincomycin HCl…4.4%
	Diary No. Date of R& I & fee	Dy.No 17733 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Lincomin-44 Powder of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 078370)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. **Each Kg Contains:** **Lincomycin as HCl…4.4%** **The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval of change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
558.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Am-Cina Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…75mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 17725 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Marko-Cena Forte Oral Liquid of M/s Vetec Laboratories, Rawat, Rawalpindi (Reg. No. 101493)

	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
559.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Z-Sel Oral Liquid
	Composition	Each 1000ml Contains: Vitamin E…150,000mg Selenium…2000mg Zinc…8000mg
	Diary No. Date of R& I & fee	Dy.No 17727 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Minerals, Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Selinozin-E Oral Liquid of M/s Nawal Pharmaceuticals, Rawalpindi. (Reg. No. 073960)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Deferred for solubility of formulation	
560.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Clafen Oral Suspension
	Composition	Each 1000ml contains: Triclabendazole…85gm Oxfendazole…22.65gm
	Diary No. Date of R& I & fee	Dy.No 17726 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Vorcid Suspension of M/s ICI Pakistan Limited, Life Sciences, Lahore. (Reg. No. 063563)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
561.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.

	Brand Name +Dosage Form + Strength	AG-Phyl Oral Liquid
	Composition	Each 100ml Contains: Doxycycline HCl…20gm Tylosin Tartrate…10gm Guaifenesin…20gm Aminophylline…8gm
	Diary No. Date of R& I & fee	Dy.No 17724 dated 21-07-2020 Rs.20,000/- dated 20-07-2020
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Tyco-G Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075704)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. **Each 100ml Contains:** **Doxycycline HCl…20gm** **Tylosin as Tartrate…10gm** **Guaifenesin…20gm** **Aminophylline…8gm** **The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval of change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
562.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Genta-St Injection 10ml
	Composition	Each ml Contains: Gentamicin as Sulphate…30mg Trimethoprim…25mg Sulphadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 16157 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Alfacin Plus Injection (10ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 049686)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
563.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Xylovetz Injection 10ml

	Composition	Each ml Contains: Xylazine HCl…23.32mg
	Diary No. Date of R& I & fee	Dy.No 16158 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Sedative, Analgesic, Muscle Relaxant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Xylax Injection (10ml) of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 078207)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. **Each ml Contains:** **Xylazine as HCl…23.32mg** **The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval of change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
564.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Xylovetz Injection 30ml
	Composition	Each ml Contains: Xylazine HCl…23.32mg
	Diary No. Date of R& I & fee	Dy.No 16146 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Sedative, Analgesic, Muscle Relaxant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml: Decontrolled
	Me-too status	Xylax Injection (30ml) of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 078207)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Decision: Approved. **Each ml Contains:** **Xylazine as HCl…23.32mg** **The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval of change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
565.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Ivovectin Injection 200ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 16155 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	200ml: Decontrolled

	Me-too status	**Could not be confirmed in the applied pack size/fill volume**
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** • Confirmation of relevant manufacturing facility (**LVP**) • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the same pack size/ fill volume as applied,** alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility (LVP)** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with the same pack size/ fill volume as applied, alongwith registration number, brand name and name of firm.**	
566.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Levanide-C Oral Liquid
	Composition	Each Liter Contains: Levamisole HCl…15gm Oxyclozanide…30gm Cobalt Sulphate Heptahydrate…3.82gm
	Diary No. Date of R& I & fee	Dy.No 16156 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 500ml,1000ml: Decontrolled
	Me-too status	Nilzan Plus Drench of M/s ICI Pakistan Limited, Life Sciences, Lahore. (Reg. No. 014555)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Liquid (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
567.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Calcimax Injection
	Composition	Each 250ml Contains: Calcium Gluconate…50gm Sodium Dimethyl-Aminomethyl Phenyl Phosphonite…1gm Magnesium Camphosulfonate…2gm Boric Acid…6gm Sorbitol…12.5gm
	Diary No. Date of R& I & fee	Dy.No 16540 dated 09-07-2020 Rs.20,000/- dated 08-07-2020
	Pharmacological Group	**Antibiotic**
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	**500ml,:** Decontrolled

	Me-too status	Calcio PH Injectable Solution of M/s Prix Pharmaceutical Lahore. (Reg. No. 018843)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid injection (General) Veterinary section** confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012. **Shortcomings**: • Evidence of manufacturing facility **Liquid injection (LVP)** • Pharmacological group mentioned in the form-5 is not correct. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for following: • **Evidence of manufacturing facility Liquid injection (LVP) section** • **Fee of Rs. 7500/- for correction/pre-approval change in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
568.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Ncs 280 Water Soluble Powder
	Composition	Each gm contains: Neomycin Sulphate…60mg Chlortetracycline HCl…200mg Streptomycin Sulphate…20mg
	Diary No. Date of R& I & fee	Dy.No 16539 dated 09-07-2020 Rs.20,000/- dated 08-07-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Pulmonil Water Soluble Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 058895)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral powder General Veterinary section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018.
	Decision: Approved. 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.	
569.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Nitrox Injection
	Composition	Each ml Contains: Nitroxynil…340mg
	Diary No. Date of R& I & fee	Dy.No 16538 dated 09-07-2020 Rs.20,000/- dated 08-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Nitroxl Forte Injection (10ml) of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid injection (General) Veterinary section** confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.

	Decision: Approved. 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.	
570.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Furosic Injection
	Composition	Each ml Contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 18530 dated 28-07-2020 Rs.20,000/- dated 28-07-2020
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml Vial: Decontrolled
	Me-too status	Furason Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112251)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. **The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval of change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
571.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Imicare Injection
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 18531 dated 28-07-2020 Rs.20,000/- dated 28-07-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml Vial: Decontrolled
	Me-too status	Dizol Injection (100ml) of M/s Manhattan Pharma, Karachi. (Reg. No. 109088)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval of change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
572.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Atrizole Drench
	Composition	Each 100ml contains: Albendazole…10gm Ivermectin…0.2gm Triclabendazole…12gm
	Diary No. Date of R& I & fee	Dy. No 18532 dated 28-07-2020 Rs.20,000/- dated 28-07-2020

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Triverzole Oral Drench of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 109985)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Oral Liquid General Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. 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.	
573.	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.
	Brand Name +Dosage Form + Strength	Doramax Injection
	Composition	Each ml Contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 16541 dated 09-07-2020 Rs.20,000/- dated 08-07-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Doracent Injection (50ml) of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 099434)
	GMP status	Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid injection (General) Veterinary section** confirmed vide letter No. F. 1-45/2009-Lic dated 27-08-2012.
	Decision: Approved. 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.	
574.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Vita D3 Plus Injection
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…40,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 15152 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Vital Forte Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 095649)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	

575.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B, P.S.I.E, Sargodha Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Bromix Plus Oral Powder
	Composition	Each Kg Powder contains: Choline Chloride…3300mg D.L Methionine…1600mg Vitamin E Acetate…4.2mg Vitamin B12…3000mg
	Diary No. Date of R& I & fee	Dy.No 17162 dated 15-07-2020 Rs.20,000/- dated 15-07-2020
	Pharmacological Group	Nutritional Supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1Kg, 2.5kg,: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Oral Powder (Non-Antibiotic/ Antibiotic) (Veterinary) Section** confirmed from panel inspection report conducted on 10-01-2019 for grant of cGMP certificate. **Shortcomings:** ormulation/drug already approved by DRAP (generic / me-too tration number, brand name and name of firm. n report (conducted within the period of last three years).
	Decision: Deferred for following: **formulation/drug already approved by DRAP (generic / me-too status) alongwith registration and name of firm.** **on report conducted within the period of last three years.** **tion**	
576.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-km, Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Tytar-50 Oral Powder
	Composition	Each 1000gm contains: Tylosin as Tartrate…500gm
	Diary No. Date of R& I & fee	Dy.No 23358 dated 11-11-2019 Rs.20,000 dated 11-11-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	500gm, 1Kg: Decontrolled
	Me-too status	Pri-Macrocid Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 080925)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Powder (General Antibiotic) Veterinary section** confirmed vide letter No. F. 1-25/2015-Lic dated 29-08-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
577.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Floxa-20 Injection 50ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 17797 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Enflox-20% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112216)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
578.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Flomax Injection 100ml
	Composition	Each ml contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 17790 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Rold Flo 30 Liquid Injection (100ml) of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109015)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
579.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Remoxon Injection 50ml
	Composition	Each ml Contains: Oxytetracycline…50mg
	Diary No. Date of R& I & fee	Dy. No 17789 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	B.G Oxy-50 Injection (50ml) of M/s Biogen Pharma, 8 Km. Chakbeli Road, Rawat. (Reg. No. 072698)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved with following label claim: **Each ml Contains:** **Oxytetracycline HCl …50mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation (completion of salt form) 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 Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.

	Brand Name +Dosage Form + Strength	Evermec Injection 20ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 17791 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml,: Decontrolled
	Me-too status	Rectin Injection (20ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 109928)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
581.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	E-Genta Injection 50ml
	Composition	Each ml Contains: Gentamycin Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 17788 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	G-Gen 100 Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 111566)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
582.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Elax-10 Injection 50ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 17792 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Melo Grand 10 Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 111553)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.

	Decision: Approved. 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.	
583.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	V-12 Injection 50ml
	Composition	Each ml contains: Cyancobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 17793 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Amvit-250 Injection (50ml) of M/s Aamster Laboratories, Rawat, Islamabad (Reg. No. 109911)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	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.	
584.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxytec 50ml Injection
	Composition	Each ml contains: Oxytetracycline eq. to Oxytetracycline dihydrate…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 17794 dated 21-07-2020 Rs.15,000/- dated 20-07-2020 & Rs.5,000/- dated 23-06-2020
	Pharmacological Group	Antibiotics, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Mine Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111571)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
585.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	B-Brone-5 Liquid
	Composition	Each 100ml contains: Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy.No 19615 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 500ml, 1Liter, 5Liter: Decontrolled
	Me-too status	Bromo Shell Liquid of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 075762)

	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012. • The applied formulation is non-pharmacopoeial.
	Decision: Approved. 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.	
586.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	E-X-200 Feed Premix
	Composition	Each 100gm contains: Oxytetracycline dihydrate…22gm
	Diary No. Date of R& I & fee	Dy.No 19614 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	500gm,1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	T-X-200 Feed Premix of M/s Delux Chemical Industries Karachi (Reg. No. 023455)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016. • Firm has claimed BP specifications while the official BP vet monograph states Oxytetracycline Veterinary oral powder is a mixture of **Oxytetracycline hydrochloride** in a suitable diluent.
	Decision: Approved. 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.	
587.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Ever-X Plus Drench
	Composition	Each ml contains: Sulphadimidine…35mg Sulphadiazine…36mg Streptomycin Sulphate…7.6mg Neomycin Sulphate…1.8mg Sodium Chloride…11.33mg Calcium Gluconate…2.2mg Magnesium Sulphate…0.6mg Potassium Chloride…3.6mg Kaolin…103.33mg Pectin…7.1mg Glycine…20.9mg
	Diary No. Date of R& I & fee	Dy.No 19619 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	No-Scour Oral Suspension of M/s Symans Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 072673)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.

	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012.
	Decision: Approved. 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.	
588.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vetzole Drench
	Composition	Each 100ml contains: Levamisole HCl…1.5gm
	Diary No. Date of R& I & fee	Dy.No 19618 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 1000ml: Decontrolled
	Me-too status	Nayverm Liquid of M/s Symans Pharmaceuticals Lahore (Reg. No. 013680)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012.
	Decision: Approved.	
589.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Fendzole Drench
	Composition	Each ml Contains: Oxfendazole…22.65mg Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 19617 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Oxfendarol C Drench of M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058793)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012.
	Decision: Approved. 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.	
590.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Walgreen Drench
	Composition	Each ml Contains: Levamisole HCl…15mg Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 19613 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 1000ml: Decontrolled

	Me-too status	Leva Act Plus Liquid of M/s Mallard Pharmaceutical (Pvt) Ltd. Multan. (Reg. No. 063777)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012.
	Decision: Approved. 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.	
591.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Oragest Powder
	Composition	Each Kg contains: Propionic Acid Calcium…250gm Propionic Acid Sodium…400gm Acetanilide…150gm Magnesium Oxide…125mg Iron II Sulphate…400mg Magnesium Sulphate…200mg Copper Sulphate…450mg Cobalt Sulphate…400mg Sodium Molybdate…100mg Sodium Chloride…20gm
	Diary No. Date of R& I & fee	Dy.No 19616 dated 11-08-2020 Rs.20,000/- dated 11-08-2020
	Pharmacological Group	Vitamins/Minerals
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Nutri-Gest Powder of M/ Zakfas Pharmaceutical (Pvt) Ltd Multan (Reg. No. 057069)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Deferred for confirmation of testing facility	
592.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	E-Flox 20 Injection 10ml
	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 23849 dated 15-09-2020 Rs.20,000/- dated 15-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Enras-20 Injection (10ml) of M/s Zakfas Pharmaceutical (Pvt) Ltd Multan (Reg. No. 057071)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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.	

593.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	E-Flox 20 Injection 50ml
	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 23851 dated 15-09-2020 Rs.20,000/- dated 15-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Enras-20 Injection (50ml) of M/s Zakfas Pharmaceutical (Pvt) Ltd Multan (Reg. No. 057071)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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.	
594.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	E-Flox 20 Injection 100ml
	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 23850 dated 15-09-2020 Rs.20,000/- dated 15-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Enras-20 Injection (100ml) of M/s Zakfas Pharmaceutical (Pvt) Ltd Multan (Reg. No. 057071)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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.	
595.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Animectin Plus Injection 50ml
	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 23848 dated 15-09-2020 Rs.20,000/- dated 15-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Ivermec 2% Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 111547)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved.	
596.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Animectin Plus Injection 10ml
	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 23847 dated 15-09-2020 Rs.20,000/- dated 15-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Ivermec 2% Injection (10ml) of M/s Grand Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 111546)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved.	
597.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	E-Cock Oral Powder
	Composition	Each Kg contains: Sulphadimidine Sodium…82500mg Sulphaquinoxaline Sodium…200,000mg Diaveridine…40,000mg Vitamin A…2,800,000 IU Vitamin K…2000mg
	Diary No. Date of R& I & fee	Dy.No 22881 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Coxicure-Ak Powder of M/s Symans Pharmaceuticals Lahore (Reg. No. 013684)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Approved. 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.	
598.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	CBS-3 Oral Powder

	Composition	Each 100gm contains: Sulphachloropyrazine Sodium Monohydrate…30gm
	Diary No. Date of R& I & fee	Dy.No 22880 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	E-Max-3 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 079125)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Approved. 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.	
599.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Fosfo 20 Plus Oral Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20gm Tylosin Tartrate…5gm Fructose…1.6gm Diphosphate…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm Sodium Chloride qs…100gm
	Diary No. Date of R& I & fee	Dy.No 22877 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Antibiotic/Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	200gm, 500gm, 1000gm: Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626) **Could not be confirmed**
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016. **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 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.	
600.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tricopure Powder
	Composition	Each 1000gm contains: Trichlorfon…0.980Kg
	Diary No. Date of R& I & fee	Dy.No 22878 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	10gm, 20gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Amsefon-980 Oral Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No.112286)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.	
601.	Name and address of manufacturer / Applicant	M/s MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Imidoxl 120 Injection 50ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 20850 dated 21-08-2020 Rs.20,000/- dated 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Himido Injection (50ml) of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No. 103945)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **Liquid Antibiotic Injectable section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
602.	Name and address of manufacturer / Applicant	M/s MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Imidoxl 120 Injection 10ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 20851 dated 21-08-2020 Rs.20,000/- dated 20-08-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Himido Injection (10ml) of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No. 103944)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **Liquid Antibiotic Injectable section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

603.	Name and address of manufacturer / Applicant	M/s MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Lignoxel Injection 50ml
	Composition	Each ml Contains: Lignocaine as HCl…2%
	Diary No. Date of R& I & fee	Dy.No 20852 dated 21-08-2020 Rs.20,000/- dated 20-08-2020
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Lignosym Injection (50ml) of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 063856)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **Liquid Antibiotic Injectable section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
604.	Name and address of manufacturer / Applicant	M/s MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Quinaxel 5 Injection
	Composition	Each vial contains: Quinapyramine Sulphate…13gm Quinapyramine Chloride…2gm
	Diary No. Date of R& I & fee	Dy.No 20855 dated 21-08-2020 Rs.20,000/- dated 20-08-2020
	Pharmacological Group	Antitrypansomial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	5gm vial; Decontrolled
	Me-too status	Pyramin Injection of M/s Manhattan Pharma Karachi (Reg. No. 052364)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **General Injectable section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Quinapyramine Sulphate…**13gm** and Quinapyramine Chloride…2gm/ 5gm vial is mentioned in label claim on Form-5 while Quinapyramine Sulphate…3gm and Quinapyramine Chloride…2gm/ 5gm is mentioned in rest of the dossier. Moreover, the reference formulation is: **Each ml contains:** **Quinapyramine Sulphate…30mg** **Quinapyramine Chloride…20mg** • The firm shall submit fee of Rs.30000/- for correction in formulation (label claim in line with reference product), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.	
605.	Name and address of manufacturer / Applicant	M/s MediExcel Pharmaceuticals, Plot No. 282, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Quinaxel 2.5 Injection
	Composition	Each vial contains: Quinapyramine Sulphate…1.5gm Quinapyramine Chloride…1gm
	Diary No. Date of R& I & fee	Dy.No 20856 dated 21-08-2020 Rs.20,000/- dated 20-08-2020
	Pharmacological Group	Antitrypansomial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	2.5gm vial; Decontrolled
	Me-too status	Quina-CS Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049638)
	GMP status	cGMP certificate dated December 2019 based on inspection conducted on **08-10-2019**.
	Remarks of the Evaluator [X]	• **General Injectable section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-10-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
606.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Adever Injection
	Composition	Each ml contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 22875 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Vitazak Injection (100ml) of M/ Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052316)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
607.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	E-Melenium Injection
	Composition	Each ml contains: Vitamin E…50mg Selenium…0.5mg
	Diary No. Date of R& I & fee	Dy.No 22879 dated 07-09-2020 Rs.20,000/- dated 04-09-2020

	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Socotel Super Injection (100ml) of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 069642)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
608.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	V-12 Injection
	Composition	Each ml contains: Cyanocobalamin…125mcg
	Diary No. Date of R& I & fee	Dy.No 22881 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial,: Decontrolled
	Me-too status	Cyanocobalamin Injection (50ml) of M/s Lawrance Pharma (Pvt) Ltd Lahore. (Reg. No. 057025)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
609.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Reboxin Injection
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 22876 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml vial,: Decontrolled
	Me-too status	Marboflox Injection (20ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088088)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
610.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Thyrodox Injection

	Composition	Each ml Contains Thiamine HCl…5mg Riboflavin…2.5mg Pyridoxine HCl…2.5mg Nicotinamide…37.5mg
	Diary No. Date of R& I & fee	Dy.No 22883 dated 07-09-2020 Rs.20,000/- dated 04-09-2020
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial,: Decontrolled
	Me-too status	Vitobion Injection (50ml) of M/s Izfaar Pharmaceutical Industries, Lahore. (Reg. No. 074747)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (General) (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic (Vol-I) dated 13-02-2020.
	Decision: Approved. 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.	
611.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Col Plus-60 Injection 100ml
	Composition	Each 100ml contains: Colistin Sulphate…60 MIU
	Diary No. Date of R& I & fee	Dy.No 22091 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Colifar Injection (100ml) of M/s Cherished Pharmaceuticals (Private) Limited, Lahore (Reg. No. 063510)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. • Provided conversion of Colistin Sulphate from MIU to grams (60MIU= 3.158gm) **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
612.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Col Plus-60 Injection 50ml
	Composition	Each 100ml contains: Colistin Sulphate…60 MIU
	Diary No. Date of R& I & fee	Dy.No 22090 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Colifar Injection (50ml) of M/s Cherished Pharmaceuticals (Private) Limited, Lahore (Reg. No. 063510)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. • Provided conversion of Colistin Sulphate from MIU to grams (60MIU= 3.158gm) **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
613.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Nitoxy-34% Injection 100ml
	Composition	Each 100ml contains: Nitroxynil…34gm
	Diary No. Date of R& I & fee	Dy.No 22088 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Nitroxl Forte Injection (100ml) of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106699)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
614.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Nitoxy-34% Injection 50ml
	Composition	Each 100ml contains: Nitroxynil…34gm
	Diary No. Date of R& I & fee	Dy.No 22087 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Nitroxl Forte Injection (50ml) of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106698)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:**

		• Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
615.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Calci-Dex Injection 300ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Magnesium Hypophosphite…5.33gm Calcium D Saccharate…1gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 22080 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Restorative, Minerals, Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	300ml: Decontrolled
	Me-too status	Dicalfon-C Injection (300ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **manufacturing facility (LVP)** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Deferred for following: • **Confirmation of relevant manufacturing facility (LVP)** • **Latest GMP inspection report (conducted within the period of last three years).**	
616.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Calci-Dex Injection 500ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Magnesium Hypophosphite…5.33gm Calcium D Saccharate…1gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 22081 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Restorative, Minerals, Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml: Decontrolled
	Me-too status	Dicalfon-C Injection (500ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **manufacturing facility (LVP)** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Decision: Deferred for following: • **Confirmation of relevant manufacturing facility (LVP)** • **Latest GMP inspection report (conducted within the period of last three years).**	

617.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Furak Injection 50ml
	Composition	Each ml Contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 22095 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Durafer Injection (50ml) of M/s Star Laboratories (Pvt) Ltd.,Lahore. (Reg. No. 108997)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change 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 A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Nitoxy-34% Injection 10ml
	Composition	Each 100ml contains: Nitroxynil…34gm
	Diary No. Date of R& I & fee	Dy.No 22086 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Nitroxl Forte Injection (10ml) of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
619.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Furak Injection 100ml
	Composition	Each ml Contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 22096 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Diuretic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Furovetz Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102017)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change 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 A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Imeclor Injection 50ml
	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…..10gm
	Diary No. Date of R& I & fee	Dy.No 22098 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Actimec Plus Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
621.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Imeclor Injection 100ml
	Composition	Each 100ml contains: Ivermectin…1gm Clorsulon…..10gm
	Diary No. Date of R& I & fee	Dy.No 22079 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Actimec Plus Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	

	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
622.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Rofox-20 Injection 50ml
	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 22084 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ceriflox 20% Injection (50ml) of M/s Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058940)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
623.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Rofox-20 Injection 100ml
	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 22085 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ceriflox 20% Injection (100ml) of M/s Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058940)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	

624.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Ak-MD Complex Injection
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Magnesium Hypophosphite…5.33gm Calcium D Saccharate…1gm Magnesium Chloride…2gm Boric Acid…4.33gm Vitamin B1…100mg Vitamin B6…70mg Vitamin 12…3000mcg Nicotinamide…200mg Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 22082 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Restorative, Minerals, Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	Calphovit Injection (300ml, 450ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 032205) **Could not be confirmed in the applied pack size/ fill volume**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **manufacturing facility (LVP)** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the applied fill volume/pack size** alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Approval of manufacturing facility (LVP)** • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with the applied fill volume/pack size alongwith registration number, brand name and name of firm.**	
625.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Sulphadin Injection
	Composition	Each 100ml contains: Sulphadimidine Sodium…33.33gm
	Diary No. Date of R& I & fee	Dy.No 22083 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	I-Sulf Injection (100ml) of M/s International Pharma Lab's Lahore (Reg. No. 052382)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:**

		• Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
626.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Neoflox-550 WSP
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 22097 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm, 250gm, 500gm, 1000gm, 5Kg,10Kg, 25Kg: Decontrolled
	Me-too status	Noxyflor Water Soluble Powder of M/s Divine Pharmaceuticals, Lahore. (Reg. No. 087584)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
627.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Fos-73 Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 22093 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibacterial, Electrolyte Balance
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078240)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved with following label claim:	

	Each 100gm contains: **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…10gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium sulphate…10gm** **Firm shall submit latest GMP inspection report conducted within the period of last three years and 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 A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Ak-C 100 Oral Powder
	Composition	Each 100gm contains: Vitamin C…100gm
	Diary No. Date of R& I & fee	Dy.No 22092 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antistress
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1000gm, 5Kg, 10Kg, 20Kg, 25Kg: Decontrolled
	Me-too status	Sannavit C-100 Oral Powder of M/s Sanna Labs Faisalabad.(Reg. No. 025368)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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 A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	CIN-SST Oral Solution
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…75mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 22089 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml, 100ml, 250ml, 500ml, 1000ml, 2.5L, 5L, 10L, 25L: Decontrolled
	Me-too status	Cina T.S Oral Suspension of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031456)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)

		• The firm has applied for "**SOLUTION"** dosage form while the referred generic product exists as **"SUSPENSION",** clarify and accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
630.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Ak-Nag Liquid
	Composition	Each 100ml contains: Norfloxacin…20gm Guaiphenesin…20gm Aminophylline…8gm
	Diary No. Date of R& I & fee	Dy.No 22094 dated 01-09-2020 Rs.20,000/- dated 01-09-2020
	Pharmacological Group	Antibiotic/ Bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml, 100ml, 150ml, 200ml, 250ml, 300ml, 500ml, 1000ml, 2.5L, 5L, 10L, 25L: Decontrolled
	Me-too status	Noramin-G Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 044976)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Referred to EWG on veterinary drugs.	
631.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ras Mineral Powder
	Composition	Each Kg contains: Vitamin A...0.80gm Vitamin D3...0.16gm Vitamin E...0.38gm Vitamin B1...1gm Vitamin B2...1.25gm Vitamin B12...0.001gm Vitamin B3...6.25gm Copper Sulphate...0.25gm Magnesium Sulphate...25gm Calcium Chloride...0.023gm Zinc Sulphate...2.17gm Manganese Sulphate...10gm Potassium Iodide...0.50gm Sodium Selenite...0.01gm D.C.P. (Phosphorous)...150gm Sodium Chloride...120gm Vitamin B6...4gm
	Diary No. Date of R& I & fee	Dy.No 20572 dated 19-08-2020 Rs.20,000/- dated 19-08-2020
	Pharmacological Group	Vitamins and Minerals
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500gm,1Kg, 5Kg, 10Kg, 25Kg; N/A

	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad. (Reg. No. 058842)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Confirmation of relevant testing facility
	Decision: Deferred for confirmation of testing facility and latest GMP inspection report conducted within the period of last three years.	
632.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Nephroflush Oral Powder
	Composition	Each gram contains: Methenamine…950mg Vitamin B1…8mg Vitamin B2…9.2mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No 22806 dated 07-09-2020 Rs.20,000/- dated 07-09-2020
	Pharmacological Group	Anti-infective and Vitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10gm, 15gm, 25gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; N/A
	Me-too status	Nephrex Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033248)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
633.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Amprocox-90 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCl…900gm
	Diary No. Date of R& I & fee	Dy.No 22808 dated 07-09-2020 Rs.20,000/- dated 07-09-2020
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; N/A
	Me-too status	Amprobar Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073955)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.

	Remarks of the Evaluator [X]	• **Oral Powder (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
634.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Syanoras Liquid
	Composition	Each 100ml contains: Tilmicosin Phosphate…25gm
	Diary No. Date of R& I & fee	Dy.No 22807 dated 07-09-2020 Rs.20,000/- dated 07-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1L, 5L, 25L; N/A
	Me-too status	Mycotil Liquid of M/s A&K Pharmaceutical, Faisalabad. (Reg. No. 049663)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change 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 Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Pri-Florecol 23 Oral Liquid
	Composition	Each Liter contains: Florfenicol…230gm
	Diary No. Date of R& I & fee	Dy.No 22246 dated 02-09-2020 Rs.20,000/- dated 02-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000ml, 5L, 10L; N/A
	Me-too status	G-Flor 23% Oral Liquid of M/s Grand Pharma (Pvt) Ltd., Rawat Islamabad (Reg. No. 082501)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid section (Veterinary)** confirmed vide letter No. F. 1-9/2000-Lic (Vol-I) dated 06-03-2019 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
636.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.

	Brand Name +Dosage Form + Strength	Doxy Plus Powder
	Composition	Each 1000gm contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Bromhexine HCl…5gm Colistin Sulphate…450 MIU Streptomycin Sulphate…36gm
	Diary No. Date of R& I & fee	Dy.No 24870 dated 23-09-2020 Rs.20,000/- dated 22-09-2020
	Pharmacological Group	Antibacterial, Anti-viral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and combination**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Conversion of Colistin Sulphate from MIU to grams.
	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.** • **Conversion of Colistin Sulphate from MIU to grams.**	
637.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	S Pro C Powder
	Composition	Each 100gm contains: **Acetylsalicyclic Acid**…20gm **Ascorbic Acid**…20gm Vitamin-K3…2.5gm
	Diary No. Date of R& I & fee	Dy.No 24872 dated 23-09-2020 Rs.20,000/- dated 22-09-2020
	Pharmacological Group	Antioxidant, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and combination**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **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 evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
638.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Tyl Co Dox Powder

	Composition	Each 100gm contains: Tylosin Tartrate…20gm Doxycycline HCl…20gm Bromhexine HCl…1gm Colistin Sulphate…3gm
	Diary No. Date of R& I & fee	Dy.No 24871 dated 23-09-2020 Rs.20,000/- dated 22-09-2020
	Pharmacological Group	Antibacterial, Anti-viral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and combination**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **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 evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
639.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fagofos Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 20574 dated 19-08-2020 Rs.20,000/- dated 18-08-2020
	Pharmacological Group	Antibiotic with diuretics
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078240)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved with following label claim: **Each 100gm contains:** **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…10gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Sulphate…10gm** **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.**	
640.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Oxy-50 Powder

	Composition	Each Kg contains: Oxytetracycline HCl…500gm
	Diary No. Date of R& I & fee	Dy.No 21333 dated 25-08-2020 Rs.20,000/- dated 18-08-2020
	Pharmacological Group	Antibacterial, Anti-infective
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Nobitet 50% Powder of M/s Noble Pharma, Mirpur Azad Kashmir. (Reg. No. 063643)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved.	
641.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Norphylin-G Liquid
	Composition	Each 100ml contains: Aminophylline…8gm Guaifenesin…20gm Norfloxacin…20gm
	Diary No. Date of R& I & fee	Dy.No 20573 dated 19-08-2020 Rs.20,000/- dated 18-08-2020
	Pharmacological Group	Antibiotic, Bronchodilator, Expectorant
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1L, 2.5L, 5L, 10L, 15L, 20L, 25L ; Decontrolled
	Me-too status	Noramin-G Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 044976)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Refer to EWG on veterinary drugs	
642.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Clormect Injection
	Composition	Each ml Contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 23856 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Ivoprem 300 Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111325)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.

	Decision: Approved. 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.	
643.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Intermox-La Injection
	Composition	Each ml Contains: Amoxicillin As Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 23857 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Novamox 20% LA Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043145)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Penicillin Liquid Injectable section (Veterinary)** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved.	
644.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Floxy Injection
	Composition	Each ml Contains: Oxytetracycline Dihydrate Eq. To Base…300mg Flunixin Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 23853 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Duasol Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No.033254)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
645.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Factofas-200 Oral Powder
	Composition	Each 100gm contains: Fosfomycin Calcium…20gm Tylosin Tartrate…5gm Fructose 1,6 Diphospahte…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm Sodium Chloride…100gm
	Diary No. Date of R& I & fee	Dy.No 23854 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Antibiotic and Mineral supplement

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 5Kg: Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
646.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Parasol-Ce Oral Powder
	Composition	Each 100gm contains: **Paracetamol**…20gm Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…1.25gm
	Diary No. Date of R& I & fee	Dy.No 23855 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Antipyretic, Vitamin and Mineral supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 5Kg: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019 **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 evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
647.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Apigest Oral Powder
	Composition	Each gram contains: Propionic Acid Calcium…250mg Propionic Acid Sodium…400mg Acetanilide…150mg Magnesium Oxide…125mg Iron II Sulphate…0.40mg Zinc Sulphate…0.10mg Magnesium Sulphate…0.20mg Copper Sulphate…0.45mg Cobalt Sulphate…0.40mg Sodium Molybdate…0.10mg Sodium Chloride…20mg
	Diary No. Date of R& I & fee	Dy.No 23852 dated 15-09-2020 Rs.20,000/- dated 11-09-2020
	Pharmacological Group	Digestive and Mineral supplement
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Gestone Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 044911)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 28-05-2019 and 19-06-2019
	Decision: Approved. 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.	
648.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Meglu Injection 10ml
	Composition	Each ml Contains: Flunixin Meglumine….50 mg
	Diary No. Date of R& I & fee	Dy.No 29637 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Analgesic, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Loxicon Injection (10ml) of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir. (Reg. No. 058704)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg** **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.**	
649.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Meglu Injection 50ml
	Composition	Each ml Contains: Flunixin Meglumine….50 mg
	Diary No. Date of R& I & fee	Dy.No 29636 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Analgesic, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Loxicon Injection (50ml) of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir. (Reg. No. 058704)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg** **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.**	

650.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Meglu Injection 100ml
	Composition	Each ml Contains: Flunixin Meglumine….50 mg
	Diary No. Date of R& I & fee	Dy.No 29635 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Analgesic, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Loxicon Injection (100ml) of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir. (Reg. No. 058704)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg** **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.**	
651.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Meglu 8.3 Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine ……83mg
	Diary No. Date of R& I & fee	Dy.No 29663 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Analgesic, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Nixsym Injection (10ml) of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….83 mg** **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.**	
652.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Meglu 8.3 Injection 50ml
	Composition	Each ml Contains: Flunixin Meglumine……83mg
	Diary No. Date of R& I & fee	Dy.No 29664 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Analgesic, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled

	Me-too status	Nixsym Injection (50ml) of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….83 mg** **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.**	
653.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Flox Rold 5 % Injection 50ml
	Composition	Each ml Contains: Enrofloxacin …..50mg
	Diary No. Date of R& I & fee	Dy.No 29631 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ceriflox Injection (50ml) of M/s Star Laboratories Lahore (Reg. No. 025703)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
654.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Flox Rold 10% Injection 50ml
	Composition	Each ml Contains: Enrofloxacin…..100mg
	Diary No. Date of R& I & fee	Dy.No 29633 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Enroxsel-10 Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049640)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
655.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Flox Rold 10% Injection 100ml
	Composition	Each ml Contains: Enrofloxacin…..100mg

	Diary No. Date of R& I & fee	Dy.No 29632 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Enroxsel-10 Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049640)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
656.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Flox Rold 20% Injection 100ml
	Composition	Each ml Contains: Enrofloxacin …..200mg
	Diary No. Date of R& I & fee	Dy.No 29666 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Quinosel Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 057009)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
657.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Flox Rold 20% Injection 50ml
	Composition	Each ml Contains: Enrofloxacin …..200mg
	Diary No. Date of R& I & fee	Dy.No 29634 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Quinosel Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 057009)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
658.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rold Flo 10% Injection 10ml

	Composition	Each ml contains: Florfenicol…..100mg
	Diary No. Date of R& I & fee	Dy.No 29620 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Florobak Injection (10ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063838)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
659.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rold Flo 10% Injection 50ml
	Composition	Each ml contains: Florfenicol…..100mg
	Diary No. Date of R& I & fee	Dy.No 29623 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Florobak Injection (50ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063838)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
660.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rold Flo 10% Injection 100ml
	Composition	Each ml contains: Florfenicol…..100mg
	Diary No. Date of R& I & fee	Dy.No 29624 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Florobak Injection (100ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063838)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	

661.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rold Flo 30% Injection 100ml
	Composition	Each 100ml contains: Florfenicol…..30gm
	Diary No. Date of R& I & fee	Dy.No 29612 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Neflox Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049648)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
662.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rold Flo 30% Injection 50ml
	Composition	Each 100ml contains: Florfenicol…..30gm
	Diary No. Date of R& I & fee	Dy.No 29625 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Neflox Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049648)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. 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.	
663.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Gent-Tyrold 600 Injection 50ml
	Composition	Each ml contains: Gentamicin Sulphate ....100mg Tylosin Tartrate ……50mg
	Diary No. Date of R& I & fee	Dy.No 29638 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	B.G. Genta Injection (50ml) of M/s Biogen Pharma. Rawat. (Reg. No. 075624)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.

	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
664.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Gent-Tyrold 600 Injection 100ml
	Composition	Each ml contains: Gentamicin Sulphate ....100mg Tylosin Tartrate ……50mg
	Diary No. Date of R& I & fee	Dy.No 29639 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	B.G. Genta Injection (100ml) of M/s Biogen Pharma. Rawat. (Reg. No. 075624)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
665.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Gent-Tyrold 75 Injection 50ml
	Composition	Each ml Contains: Gentamicin Sulphate ….25mg Tylosin Tartrate ……50mg
	Diary No. Date of R& I & fee	Dy.No 29668 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Tylogenta Injection (50ml) of M/s Biogen Pharma. Rawat. (Reg. No. 049775)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
666.	Name and address of manufacturer / Applicant	Haarolds Pharmaceuticals (Private) Limited, Plot No 58 59 60 61 62 63 64C Small Industrial Estate Bhimber, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Gent-Tyrold 75 Injection 100ml
	Composition	Each ml Contains: Gentamicin Sulphate ….25mg Tylosin Tartrate ……50mg
	Diary No. Date of R& I & fee	Dy.No 29667 dated 06-11-2020 Rs.20,000 dated 05-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Tylogenta Injection (100ml) of M/s Biogen Pharma.

		Rawat. (Reg. No. 049775)
	GMP status	Panel inspection conducted on 09-10-2020 for grant of DML.
	Remarks of the Evaluator [X]	**Liquid Injection Section (Veterinary) General** confirmed from panel inspection report for grant of DML based on inspection conducted on 09-10-2020.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
667.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gentamox Forte Injection 50ml
	Composition	Each ml contains: Amoxicillin as Amoxicillin Trihydrate…150mg Gentamycin As Gentamycin Sulphate…40mg
	Diary No. Date of R& I & fee	Dy.No 27766 dated 20-10-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Amoxygent Forte Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 097945)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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.	
668.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gentamox Forte Injection 100ml
	Composition	Each ml contains: Amoxicillin as Amoxicillin Trihydrate…150mg Gentamycin As Gentamycin Sulphate…40mg
	Diary No. Date of R& I & fee	Dy.No 27767 dated 20-10-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Amoxygent Forte Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 097946)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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.	
669.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Biopent Forte Injection 15ml

	Composition	Each ml contains: Procaine Penicillin …1,500,000 IU Benzyl Penicillin …500,000 IU Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 27762 dated 20-10-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	15ml: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Clarification regarding applied formulation is required since same quantities of APIs are mentioned "**per ml"** on cover letter and **"per vial (15 ml)"** on form 5; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The firm shall submit fee of Rs.30000/- for correction in formulation (label claim in line with reference product), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Provide conversion of Procaine Penicillin and Benzyl Penicillin from IU to grams.
	Decision: Deferred for following: • **Clarification of applied formulation** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Conversion of Procaine Penicillin and Benzyl Penicillin from IU to grams**	
670.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Biopent Forte Injection 50ml
	Composition	Each ml contains: Penicillin G Procaine …3,000,000 IU Penicillin G Sodium …1,000,000 IU Dihydro Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 27763 dated 20-10-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Clarification regarding applied formulation is required since same quantities of APIs are mentioned "**per ml"** on cover letter and **"per vial (50 ml)"** on form 5; and provide accordingly evidence of applied formulation/drug already

		approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The firm shall submit fee of Rs.30000/- for correction in formulation (label claim in line with reference product), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Provide conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams.
	Decision: Deferred for following: • **Clarification of applied formulation** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams**	
671.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxanic 100ml Injection
	Composition	Each ml Contains: Amoxicillin as Amoxicillin Trihydrate…140mg Clavulanic Acid as Potassium Clavulanate…35mg
	Diary No. Date of R& I & fee	Dy.No 28565 dated 27-10-2020 Rs.20,000/- dated 23-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Nugmentan Injection (100ml) of M/s Nawan Laboratories (Pvt) Ltd., Karachi (Reg. No. 072675)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved	
672.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxanic 50ml Injection
	Composition	Each ml Contains: Amoxicillin as Amoxicillin Trihydrate…140mg Clavulanic Acid as Potassium Clavulanate…35mg
	Diary No. Date of R& I & fee	Dy.No 28564 dated 27-10-2020 Rs.20,000/- dated 23-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Nugmentan Injection (50ml) of M/s Nawan Laboratories (Pvt) Ltd., Karachi (Reg. No. 072675)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved.	
673.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad

	Brand Name +Dosage Form + Strength	Dimet Injection 100ml
	Composition	Each ml Contains: Tyosin Tartrate…50mg Colistin Sulphate…10mg Dimetridazole…100mg
	Diary No. Date of R& I & fee	Dy.No 28563 dated 27-10-2020 Rs.20,000/- dated 23-10-2020
	Pharmacological Group	Antibiotic and Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Mettycoli Injection (100ml) of M/s. Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080728)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
674.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dimet Injection 50ml
	Composition	Each ml Contains: Tyosin Tartrate…50mg Colistin Sulphate…10mg Dimetridazole…100mg
	Diary No. Date of R& I & fee	Dy.No 28562 dated 27-10-2020 Rs.20,000/- dated 23-10-2020
	Pharmacological Group	Antibiotic and Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Dicotyl Injection (50ml) of M/s Izfaar Pharmaceutical Industries, Lahore. (Reg. No. 074741)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
675.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bio-Oxicillin Injection 50ml
	Composition	Each ml Contains: Amoxicillin as Amoxicillin Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 27764 dated 20-10-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Novamox 20% LA Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043145)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved.	
676.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Hilfos Injection 50ml
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…50mcg Taurine…37.3mg Nicotinamide…23mg DL Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No 27130 dated 14-10-2020 Rs.20,000/- dated 12-10-2020
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Fospho-AV Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 088084)
	GMP status	cGMP certificate dated 24-01-2023 based on inspection dated 23-01-2023
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (General) section** confirmed vide panel inspection dated 23-01-2023 for issuance of cGMP certificate
	Decision: Approved	
677.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Hilfos Injection 100ml
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…50mcg Taurine…37.3mg Nicotinamide…23mg DL Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No 27131 dated 14-10-2020 Rs.20,000/- dated 12-10-2020
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Fospho-AV Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 099370)
	GMP status	cGMP certificate dated 24-01-2023 based on inspection dated 23-01-2023
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (General) section** confirmed vide panel inspection dated 23-01-2023 for issuance of cGMP certificate
	Decision: Approved	
678.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad

	Brand Name +Dosage Form + Strength	Piram Powder
	Composition	Each 100gm powder contains: Spiramycin…50MIU Trimethoprim…5gm
	Diary No. Date of R& I & fee	Dy.No 28442 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Sirova Powder of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 074011)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of **Shortcomings:** Spiramycin from MIU to grams.
	Decision: Approved. 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 and conversion of Spiramycin from MIU to grams before issuance of registration letter.	
679.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Amedox-50% Powder
	Composition	Each 100gm contains: Doxycycline Hyclate…50gm
	Diary No. Date of R& I & fee	Dy.No 28441 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Z-Doxy 50% Water Soluble Powder of M/s Zoic International, Lahore. (Reg. No. 080947)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
680.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Amsebel Powder
	Composition	Each 100g Contains: Furosemide…2gm **Belladonna Extract**…0.2gm
	Diary No. Date of R& I & fee	Dy.No 28444 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Diuretic/ Antispasmodic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled

	Me-too status	Flush B Powder of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad. (Reg. No. 075742)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Registration Board referred the instant application to Committee on "Grey area molecules."	
681.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Aminor-G Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…100mg Guaifenesin…40mg Aminophylline…100mg
	Diary No. Date of R& I & fee	Dy.No 28443 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibiotic, Expectorant, Bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Ensol-AG Oral Liquid of M/s Biogen Pharma, Rawat (Reg. No. 049720)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
682.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Cina-Flox Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…75mg Sulphamethoxypyridazine…50mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 28439 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad (Reg. No. 074786)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of

	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
683.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Amcol 20% Oral Liquid
	Composition	Each ml Contains: Colistin Sulphate…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 28436 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Racol Oral Liquid of M/s Nawal Pharmaceuticals, Rawalpindi (Reg. No. 078254)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Liquid Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
684.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	L-Con 44 Powder
	Composition	Each 100g Contains: Lincomycin HCl…44g
	Diary No. Date of R& I & fee	Dy.No 28438 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Licogrow-44 Oral Powder of M/s Ras Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 080157)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
685.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Amiflor-50 W/S Powder
	Composition	Each gm contains: Florfenicol…500mg
	Diary No. Date of R& I & fee	Dy. No 28437 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Naflor Powder of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 049513)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
686.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ami-Coc W/S Powder
	Composition	Each gm contains: Amprolium HCl…200mg Sulphaquinoxaline Base…200mg Menadione Sodium Bisulphite…2mg
	Diary No. Date of R& I & fee	Dy.No 28440 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg; Decontrolled
	Me-too status	Max-Coc Powder of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 063708)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of
	Decision: Approved. 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.	
687.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	NCC-Bro Powder
	Composition	Each 1000gm contains: Neomycin Sulphate…70gm Colistin Sulphate…4gm Chlortetracycline HCl…80gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy.No 28435 dated 26-10-2020 Rs.20,000/- dated 26-10-2020
	Pharmacological Group	Antibacterial, Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	NB-CIN Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad. (Reg. No. 078359)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	**-I and Oral Powder Section-II (Veterinary)** confirmed vide rt based on inspection conducted on 05-09-2019 for grant of

	Decision: Approved. 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.	
688.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Misole-50 Powder
	Composition	Each 1000gm powder contains: Levamisole HCl…500gm
	Diary No. Date of R& I & fee	Dy.No 28074 dated 22-10-2020 Rs.20,000/- dated 22-10-2020
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30gm, 50gm, 100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Anthiy Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 044964)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	**…l) Section (Veterinary)** confirmed vide panel inspection report …nducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. 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.	
689.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	N-Ro 20 Liquid
	Composition	Each 1000ml contains: Enrofloxacin…200gm
	Diary No. Date of R& I & fee	Dy.No 28073 dated 22-10-2020 Rs.20,000/- dated 22-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter; Decontrolled
	Me-too status	Lexi-Enroks Liquid of M/s Lexicon Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 046675)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	**…ral) (Veterinary)** confirmed vide panel inspection report based …ed on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. 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.	
690.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Vital-EZ Oral Liquid
	Composition	Each 1000ml Contains: Vitamin E…150,000mg Selenium (Sodium Selenite) …2000mg Zinc (Zinc Sulphate)…8000mg
	Diary No. Date of R& I & fee	Dy.No 26587 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Immune enhancer/tonic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	30ml, 60ml, 100ml, 250ml, 500ml, 1000ml, 2.5L, 5L, 10L, 25L: Decontrolled
	Me-too status	Vestol-200 Oral Liquid of M/s Sanna Laboratories, Faisalabad. (Reg. No. 078273)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
691.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Akoxy 95 Powder
	Composition	Each Kg contains: Oxytetracycline HCl…950gm
	Diary No. Date of R& I & fee	Dy.No 26596 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Oxymix Powder of M/s Symans Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 023439)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
692.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Akchlor 80 Powder
	Composition	Each 1000gm contains: Chlortetracycline HCl…80gm Neomycin Sulphate…70gm Colistin Sulphate…4gm
	Diary No. Date of R& I & fee	Dy.No 26595 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm, 250gm, 500gm, 1000gm, 5Kg, 10Kg: Decontrolled
	Me-too status	SB Neocotin Soluble Powder of M/s SB Pharma, Islamabad (Reg. No. 109882)
	GMP status	

	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
693.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tylofos Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20gm Tylosin Tartrate…5gm Fructose 1,6 Diphosphate…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm Sodium Chloride qs…100gm
	Diary No. Date of R& I & fee	Dy.No 26589 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibacterial, Electrolyte
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi (Reg. No. 075626)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved with following label claim: **Each 100gm contains:** **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…5gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Phoshate…10gm** **Sodium Chloride qs…100gm** **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 and latest GMP inspection report (conducted within the period of last three years, before issuance of registration letter.**	
694.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Oxicin 150 Powder
	Composition	Each 1000gm contains: Oxytetracycline HCl…80gm Neomycin Sulphate…70gm
	Diary No. Date of R& I & fee	Dy.No 26592 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	10gm, 30gm, 100gm, 250gm, 500gm, 1000gm, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Oxcinobak Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075717)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
695.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Dicla-5 Premix
	Composition	Each 1000gm contains: Diclazuril…5gm
	Diary No. Date of R& I & fee	Dy.No 26586 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Myoclor Premix of M/s Myrtle Pharma, Karachi. (Reg. No. 072615)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
696.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Colicin 550 WSP
	Composition	Each gm contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 26594 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm, 250gm, 500gm, 1000gm, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Noxyflor Water Soluble Powder of M/s Divine Pharmaceuticals, Lahore. (Reg. No. 087584)
	GMP status	

	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
697.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Dialpha Plus Powder
	Composition	Each Kg contains: Sulphadimerazine…860gm Diaveridine…105gm Vitamin K3…2000mg
	Diary No. Date of R& I & fee	Dy.No 26593 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic, Antiprotozoal, Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm, 250gm, 500gm, 1000gm, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Duo Cox Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046666)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
698.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bio-Oxicillin Injection 100ml
	Composition	Each ml Contains: Amoxicillin as Amoxicillin Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 27765 dated 20-10-2020 Rs.20,000/- dated 24-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Novamox 20% LA Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043145)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved	

699.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Genak-20 Injection 100ml
	Composition	Each ml contains: Gentamicin as Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 26602 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Genta-Rus 20% Injection (100ml) of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031467)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
700.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Genak-20 Injection 50ml
	Composition	Each ml contains: Gentamicin as Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 26601 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Genta-Rus 20% Injection (50ml) of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031467)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
701.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Adeka-140 Injection 100ml
	Composition	Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 26600 dated 09-10-2020 Rs.20,000/- dated 09-10-2020

	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	VAD3 Injection (100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059179)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. (Vitamin A 80,000IU = 44mg, VitaminD3 40,000 IU= 1mg) **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
702.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Adeka-140 Injection 50ml
	Composition	Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 26599 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	VAD3 Injection (50ml) of M/s Breeze Pharma Islamabad (Reg. No. 059179)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. (Vitamin A 80,000IU = 44mg, VitaminD3 40,000 IU= 1mg) **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
703.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Brocin Injection
	Composition	Each ml contains: Enrofloxacin…50mg
	Diary No. Date of R& I & fee	Dy.No 26590 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Ceriflox Injection (50ml) of M/s Star Laboratories Lahore. (Reg. No. 025703)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
704.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Akflox Injection 100ml
	Composition	Each 100ml Contains: Levofloxacin as Hemihydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 26591 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the 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.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the 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.**	
705.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Makflox Injection 20ml
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 26588 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml vial: Decontrolled
	Me-too status	Marboflox Injection (20ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088088)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018.

		Shortcomings: • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
706.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Mectin-D Injection 100ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 26598 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Doravect Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113557)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
707.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Mectin-D Injection 50ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 26597 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Doracent Injection (50ml) of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 099434)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
708.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.

	Brand Name +Dosage Form + Strength	Meta-Amino Forte Injection
	Composition	Each ml contains: DL-Acetylmethionine…200mg Cyanocobalamin…0.2mg L-Carnitine (HCl)…50mg Alpha-Tocopherol (Acetate)…30mg
	Diary No. Date of R& I & fee	Dy.No 26605 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Sterivit Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 095650)
	GMP status	
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. 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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
709.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Meta-Amino Injection 250ml
	Composition	Each 100ml Contains: L-Carnitine…500mg Thioctic Acid…20mg Pyridoxine HCl…15mg Cyanocobalamin…3mg DL-Acetylmethionine…2000mg L-Arginine…240mg L-Ornithine…120mg L-Citruline…120mg L-Lysine…50mg Glycine...150mg Taurine...150mg Aspartic Acid...150mg Glutamic Acid...150mg Fructose...5000mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 26603 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml vial: Decontrolled
	Me-too status	Vetzpower Injection (250ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.088074)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid injectable (LVP) (General) section** by CLB
	Decision: Deferred for following:	

	• **Latest GMP inspection report (conducted within the period of last three years).** • **Approval of Liquid injectable (LVP) (General) section by CLB**	
710.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Meta-Amino Injection 500ml
	Composition	Each 100ml Contains: L-Carnitine…500mg Thioctic Acid…20mg Pyridoxine HCl…15mg Cyanocobalamin…3mg DL-Acetylmethionine…2000mg L-Arginine…240mg L-Ornithine…120mg L-Citruline…120mg L-Lysine…50mg Glycine...150mg Taurine...150mg Aspartic Acid...150mg Glutamic Acid...150mg Fructose...5000mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 26604 dated 09-10-2020 Rs.20,000/- dated 09-10-2020
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml vial: Decontrolled
	Me-too status	Vetzpower Injection (500ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102020)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid injectable (LVP) (General) section** by CLB
	Decision: Deferred for following: • **Latest GMP inspection report (conducted within the period of last three years).** • **Approval of Liquid injectable (LVP) (General) section by CLB**	
711.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Animectin 1% Injection 100ml
	Composition	Each ml Contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 31062 dated 23-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Ivoron Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112244)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved	

712.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bio-E-Floxacin 10% Injection 50ml
	Composition	Each ml Contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 31063 dated 23-11-2020 Rs.20,000/- dated 19-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Enroxsel-10 Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049640)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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.	
713.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Spiracin Injection
	Composition	Each ml Contains: Lincomycin HCl…75mg Spiramycin adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 30860 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	**50ml, 100ml**: Decontrolled
	Me-too status	Lincospira Injection (50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 046570)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both **100ml and 50ml** pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved. Firm shall choose any one fill volume of 100ml or 50ml before issuance of registration letter. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
714.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hepacare Injection 100ml

	Composition	Each ml Contains: Phenoxy-2-Methyl-2-Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 30859 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Hepatoprotectant
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	**50ml, 100ml**: Decontrolled
	Me-too status	Bio-Hepa Injection (50ml) of M/s Biorise Pharmaceuticals, Multan (Reg. No. 112182) Bio-Hepa Injection (100ml) of M/s Biorise Pharmaceuticals, Multan (Reg. No. 112183)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both **100ml and 50ml** pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved. Firm shall choose any one fill volume of 100ml or 50ml before issuance of registration letter.	
715.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bioflunix Injection
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 30861 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Anti-pyretic/ Analgesic/ NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	**50ml, 100ml**: Decontrolled
	Me-too status	Fluxim-5% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 109943) Fluxim-5% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 109944)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both **100ml and 50ml** pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved with following label claim **Each ml contains:** **Flunixin as Meglumine…50mg**	

	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 and choose any one fill volume of 100ml or 50ml before issuance of registration letter.	
716.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Biosulphate Injection
	Composition	Each ml contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 30862 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	**25ml, 50ml**: Decontrolled
	Me-too status	Atopin Injection (25ml, 50ml) of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore.(Reg. No. 062122)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both **25ml and 50ml** pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved. Firm shall choose any one fill volume of 25ml or 50ml before issuance of registration letter.	
717.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bromotec Powder
	Composition	Each 100gm contains: Bromhexine HCl…1g Tartaric Acid…15g
	Diary No. Date of R& I & fee	Dy.No 30958 dated 20-11-2020 Rs.20,000/- dated 20-11-2020
	Pharmacological Group	Bronchodilator, mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Bromotaric Water Soluble Powder of M/s ICI Pakistan Limited, Life Sciences, Lahore (Reg. No. 089822)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	**al) Section (Veterinary)** confirmed vide panel inspection tion conducted on 31-03-2021 & 08-04-2021 for renewal of
	Decision: Approved. 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.	
718.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ty Fos Powder

	Composition	Each 100gm of Powder Contains: Fosfomycin Calcium…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy.No 30639 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30gm, 50gm, 100gm, 250gm, 500gm,1Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Fosomax Oral Powder of M/s Biogen Pharma, Rawat (Reg. No. 063808)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	**al) Section (Veterinary)** confirmed vide panel inspection tion conducted on 31-03-2021 & 08-04-2021 for renewal of
	Decision: Approved with following label claim: **Each 100gm contains:** **Fosfomycin Calcium …20gm** **Tylosin as Tartrate…10gm** **Fructose 1,6 Diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Sulphate…10gm** **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.**	
719.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dimarina Injection
	Composition	Each ml Contains: Diminazine Aceturate…105mg **Antipyrine**…131mg
	Diary No. Date of R& I & fee	Dy.No 31452 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Durazene Easy Injection (10ml, 20ml, 50ml, 100ml) of Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074017)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Initially, multiple pack sizes (10ml, 20ml, 50ml, 100ml, 450ml and 500ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml** pack size.
	Decision: Deferred for review by expert working group for veterinary drugs.	
720.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Anical Injection

	Composition	Each ml Contains: Calcium Gluconate…38.71gm Boric Acid…7.29gm Calcium Hydroxide…1.32gm Magnesium Chloride…6.50gm
	Diary No. Date of R& I & fee	Dy.No 31451 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Calcium and Magnesium supplementary source for energy
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 450ml, 500ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and combination**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal s granted to separate pack size/fill volume of injectable dosage ble pack sizes of injectable dosage form are demanded in a single cation is required for which pack size/ fill volume you want to d accordingly provide evidence of applied formulation/drug DRAP (generic / me-too status) alongwith registration number, of firm.
	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.	
721.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fruselite Powder
	Composition	Each Kg contains: Furosemide…20gm Manganese Sulphate…6gm Sodium Chloride…10gm Potassium Chloride…10gm
	Diary No. Date of R& I & fee	Dy.No 27761 dated 20-10-2020 Rs.20,000/- dated 20-10-2020
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Frusavet Oral Powder of M/s Westmont Pharmaceutical Industry Rawalpindi. (Reg. No.058932)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
722.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Ampro Farm Powder
	Composition	Each 1000gm contains: Amprolium HCl…900gm
	Diary No. Date of R& I & fee	Dy.No 30863 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Anticoccidial

	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Amprobar Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 073955)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved.	
723.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Tylomax Powder
	Composition	Each 100gm Powder Contains: Tylosin Tartrate…98gm
	Diary No. Date of R& I & fee	Dy.No 30864 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Amsetyl-98 Oral Water Soluble Powder of M/s Aamster Laboratories, Rawat, Islamabad (Reg. No. 101999)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
724.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Oxyfag Powder
	Composition	Each 100gm Powder Contains: Oxytetracycline HCl…95gm
	Diary No. Date of R& I & fee	Dy.No 30865 dated 19-11-2020 Rs.20,000/- dated 17-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Oxymix Powder of M/s Symans Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 023439)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved.	
725.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Tribentin Suspension
	Composition	Each 100ml Contains: Albendazole…10gm Ivermectin…0.2gm

		Triclabendazole…12gm
	Diary No. Date of R& I & fee	Dy.No 27760 dated 20-10-2020 Rs.20,000/- dated 20-10-2020
	Pharmacological Group	Anti-parasitic, Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5 Liter, 5 Liter, 10 Liter, 15 Liter, 20 Liter, 25 Liter; Decontrolled
	Me-too status	Thunder Drench of M/s Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058941)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral liquid General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved.	
726.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Combigent Injection 50ml
	Composition	Each 100ml Contains: Gentamycin Sulphate…5gm Tylosin Tartrate…10gm Colistin Sulphate…20 MIU
	Diary No. Date of R& I & fee	Dy.No 29492 dated 05-11-2020 Rs.20,000/- dated 05-11-2020
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	C-Tylo G Injection of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102015
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	• **Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. • Provided conversion of Colistin Sulphate from MIU to grams.(1MIU=50mg)
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
727.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Almox LA 20% Injection 100ml
	Composition	Each ml Contains: Amoxicillin as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 30030 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Amocillin 20% LA Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113598)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.

	Remarks of the Evaluator [X]	The firm has claimed BP specifications while **BP monograph** states that Amoxicillin injection is a sterile solution of **Amoxicillin Sodium in Water for injection.** • **Liquid Injectable (Penicillin) veterinary** section confirmed vide panel inspection report dated 14-12-2015 for renewal of DML
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
728.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Almox LA 20% Injection 50ml
	Composition	Each ml Contains: Amoxicillin as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 30036 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP vet specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Amocillin 20% LA Injection (50ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113597)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	The firm has claimed BP specifications while **BP monograph** states that Amoxicillin injection is a sterile solution of **Amoxicillin Sodium in Water for injection.** • **Liquid Injectable (Penicillin) veterinary** section confirmed vide panel inspection report dated 14-12-2015 for renewal of DML
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
729.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenoxy L-A Injection 100ml
	Composition	Each 1ml Contains: Oxytetracycline as HCl…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 30034 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketocin Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 102101)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

730.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Fenoxy L-A Injection 50ml
	Composition	Each 1ml Contains: Oxytetracycline as HCl…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 30037 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial/ NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
731.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Enro Coli 10gm Oral Powder
	Composition	Each 10gm Contains: Enrofloxacin…2000mg Colistin Sulphate…450,0000 IU
	Diary No. Date of R& I & fee	Dy.No 30035 dated 10-11-2020 Rs.20,000/- dated 10-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm; Decontrolled
	Me-too status	Encowim Powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 099288)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Oral Dry Powder sachet (veterinary) section** confirmed vide panel inspection report dated 21-01-2020 to 24-01-2020 to check cGMP compliance • Provided conversion of Colistin Sulphate from IU to grams.(1mg=24000IU)
	Decision: Approved. 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.	
732.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Tylo 200 Injection 100ml
	Composition	Each ml Contains: Tylosin Tartrate Eq. To Tylosin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 25135 dated 25-09-2020 Rs.20,000/- dated 25-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled

	Me-too status	Tylo-Rus 20% Injection (100ml) of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031465)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised Form-5 alongwith fee Rs. 30,000/- dated 07-03-2023 vide slip No. 371024351181 for change of title.
	Decision: Approved	
733.	Name and address of manufacturer / Applicant	M/s Lucky Core Industries Limited, 45-KM, off Multan Road, Lahore. (Formerly, ICI Pakistan Limited Life Sciences)
	Brand Name +Dosage Form + Strength	Tylo 200 Injection 50ml
	Composition	Each ml Contains: Tylosin Tartrate Eq. To Tylosin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 25136 dated 25-09-2020 Rs.20,000/- dated 25-09-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Tylo-Rus 20% Injection (50ml) of M/s Vety-Care Pharmaceutical (Pvt) Ltd., Islamabad. (Reg. No. 031465)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Veterinary** section granted vide letter No. F.1-41/2007-Lic dated 10-07-2017 • The firm has submitted revised form-5 along with Fee Rs. 30,000/- dated 07-03-2023 vide slip No. 5432156514 for change of title.
	Decision: Approved	
734.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Imuhil Powder
	Composition	Each gram contains: **Lysozyme**…22% Vitamin E 50 SD…0.5%
	Diary No. Date of R& I & fee	Dy.No 11471 dated 10-07-2019 Rs.20,000/- dated 09-07-2019
	Pharmacological Group	Enzyme/Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm: Decontrolled
	Me-too status	Vitozyme Powder of M/s Selmore Pharmaceuticals (Pvt.) Ltd., Lahore. (Reg. No. 049622)
	GMP status	cGMP certificate dated 24-01-2023 based on inspection dated 23-01-2023
	Remarks of the Evaluator [X]	**Dry powder Veterinary section** confirmed vide panel inspection dated 23-01-2023 for issuance of cGMP certificate
	Decision: Deferred for rationality and solubility of formulation	
735.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Buprafas Injection

	Composition	Each ml Contains: Bupravaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 27127 dated 14-10-2020 Rs.20,000/- dated 14-10-2020
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Eter Bupra Injection (50ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 109843)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Approved. 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.	
736.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Oxy-Pro Injection
	Composition	Each ml Contains: Oxytetracycline HCl…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 27128 dated 14-10-2020 Rs.20,000/- dated 14-10-2020
	Pharmacological Group	Antibacterial/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
737.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited, 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Meloxifas-10 Injection
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 27129 dated 14-10-2020 Rs.20,000/- dated 14-10-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Meloxi-10 Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049643)
	GMP status	cGMP Inspection conducted on 08-10-2020 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injectable (General) (Veterinary) section** confirmed vide letter No. F.1-37/2004-Lic (Vol-I) dated 04-10-2019.

	Decision: Approved. 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.	
738.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Colimoxin Forte Injection 100ml
	Composition	Each ml Contains: Amoxicillin Eq. To Amoxicillin Trihydrate…140mg Colistin Sulphate…0.3 MIU
	Diary No. Date of R& I & fee	Dy.No 26585 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Moxil-C 50ml Injection **(50ml)** of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 085491) **Could not be confirmed in the applied fill volume/ pack size**
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Dry powder for injection (Penicillin) and liquid injection (Penicillin) Veterinary section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019 • Provided conversion of Colistin Sulphate from MIU to grams. (1MIU=50mg) **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with **same fill volume/ pack size as applied**, alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same fill volume/ pack size as applied, alongwith registration number, brand name and name of firm.	
739.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Colimoxin Forte Injection 50ml
	Composition	Each ml Contains: Amoxicillin Eq. To Amoxicillin Trihydrate…140mg Colistin Sulphate…0.3 MIU
	Diary No. Date of R& I & fee	Dy.No 26573 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Moxil-C 50ml Injection (50ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 085491)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Dry powder for injection (Penicillin) and liquid injection (Penicillin) Veterinary section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019 Provided conversion of Colistin Sulphate from MIU to grams. (1MIU=50mg)

	Decision: Approved. 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.	
740.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Prostenol Injection 20ml
	Composition	Each ml contains: Cloprostenol Sodium 263mcg eq. to Cloprostenol…250mcg
	Diary No. Date of R& I & fee	Dy.No 26582 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Ovuprost Injection (20ml) of M/s Ghazi Brothers, Karachi. (Reg. No. 099427)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid injection (Hormone) Veterinary section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019
	Decision: Approved	
741.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Trilox Injection 100ml
	Composition	Each ml contains: Gentamicin Sulphate…30mg Sulphadimidine…125mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 26568 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Flax Injection (100ml) of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 097900)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
742.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Trilox Injection 50ml
	Composition	Each ml contains: Gentamicin Sulphate…30mg Sulphadimidine…125mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 26567 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Genta-Prim Injection (50ml) of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 080520)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
743.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Odemtic Injection 10ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 26576 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Furovetz Injection (10ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102017)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
744.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Lincotin Injection 100ml
	Composition	Each ml contains: Lincomycin as HCl…50mg Spectinomycin as Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 26563 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Biseptyl Solution for Injection (100ml) of M/s Selmore Pharmaceuticals Pvt Ltd., Lahore (Reg. No. 109962)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved. 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.	

745.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Clofenac Injection 10ml
	Composition	Each ml contains: Aceclofenac Sodium eq. to Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 26574 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Afonac Injection (10ml) of M/s Mylab (Pvt) Ltd, Bahawalpur (Reg. No. 095656)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. **Shortcomings:** • Firm has mentioned salt form while the reference formulation is **Each ml contains:** **Aceclofenac.....25mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Referred to EWG on veterinary drugs to review environment safety requirements Discuss	
746.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Flumix Bolus
	Composition	Each bolus contains: Flumequine…350mg
	Diary No. Date of R& I & fee	Dy.No 26581 dated 09-10-2020 Rs.20,000/- dated 08-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, 50's, 100's: Decontrolled
	Me-too status	Flumexcel 350 Bolus of M/s Mediexcel Pharmaceuticals, Islamabad (Reg. No. 106712)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	• **Bolus Veterinary section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019
	Decision: Approved. 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.	
747.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Clomisol Injection
	Composition	Each ml Contains: Levamisol as HCl…100mg Closental Sodium Di-Hydrate…5mg

	Diary No. Date of R& I & fee	Dy.No 31453 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	**10ml, 20ml, 50ml, 100ml, 450ml, 500ml**: Decontrolled
	Me-too status	
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with **same fill volume/ pack size as applied**, alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same fill volume/ pack size as applied, alongwith registration number, brand name and name of firm.	
748.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Resflo Injection
	Composition	Each ml Contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 31454 dated 26-11-2020 Rs.20,000/- dated 26-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml, 450ml, 500ml: Decontrolled
	Me-too status	Neflox Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049648)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Initially, multiple pack sizes (10ml, 20ml, 50ml, 100ml, 450ml and 500ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml** pack size.
	Decision: Approved with 50ml pack size. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
749.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Propion 100mg/ml Injection
	Composition	Each ml Contains: Phenoxy-2-Methyl-2-Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 31247 dated 24-11-2020 Rs.20,000/- dated 24-11-2020
	Pharmacological Group	Liver tonic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Hepaguard Injection (100ml) of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 063624)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid injectable (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of DML renewal
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
750.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Eltylogen Injection
	Composition	Each ml Contains: Tylosin Tartrate…100mg Gentamicin as Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 31247 dated 24-11-2020 Rs.20,000/- dated 24-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Tygent Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049636)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid injectable (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of DML renewal
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
751.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Amocin-Powder
	Composition	Each Kg Contains: Amoxicillin Trihydrate…200gm Spectinomycin…88gm Lincomycin HCl…88gm Vitamin E…30gm
	Diary No. Date of R& I & fee	Dy.No 28798 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Salt form completion; and provide accordingly 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: • **Confirmation of manufacturing facility**	

	• **Latest GMP inspection report (conducted within the period of last three years).** • **Salt form completion; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status), alongwith registration number, brand name and name of firm.**	
752.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avimox-20 Powder
	Composition	Each 1000gm contains: Amoxicillin…200gm
	Diary No. Date of R& I & fee	Dy.No 28799 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Bioxil 20% Powder of M/s Biorex Pharmaceuticals, Islamabad. (Reg. No. 034586)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of Penicillin powder section by CLB • The firm has applied for Amoxicillin…200gm/1000gm however, the reference formulation is • **Each 100gm contains:** **Amoxycillin (as Trihydrate) …20gm** • Firm shall submit fee of Rs.30000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for following: • **Confirmation of manufacturing facility** • **Latest GMP inspection report (conducted within the period of last three years).**	
753.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Amanda-10 Powder
	Composition	Each Kg contains: **Amantadine HCl**…100gm
	Diary No. Date of R& I & fee	Dy.No 28789 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Antamits Water Soluble Powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 078316)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
754.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Vita-C Plus Powder

	Composition	Each Kg contains: **Paracetamol**…20gm Vitamin C…200gm Calcium Carbonate…45gm Magnesium Sulphate…35gm Potassium Chloride…40gm
	Diary No. Date of R& I & fee	Dy.No 28788 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antipyretic/ Electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
755.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Necosin Powder
	Composition	Each Kg Contains: Neomycin Sulphate…200gm Oxytetracycline Hcl…200gm Colistin Sulphate…12.631gm
	Diary No. Date of R& I & fee	Dy.No 31826 dated 30-11-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the 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.
	Decision: Deferred for following: • **Latest GMP inspection report (conducted within the 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.**	
756.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Doxina-Powder
	Composition	Each Kg Contains: Tylosin Tartrate…100gm Colistin Sulphate…500MIU Bromhexine HCl…5gm Doxycycline HCl…200gm

	Diary No. Date of R& I & fee	Dy.No 28800 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Respisin Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 089827)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Colistin Sulphate from MIU to grams.
	Decision: Approved. The firm shall submit the following before issuance of registration letter • **fee of Rs. 30,000/- for correction/pre-approval change in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **latest GMP inspection report conducted within the period of last three years** • **conversion of Colistin Sulphate from MIU to grams**	
757.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Cinadox-50 Powder
	Composition	Each Kg contains: Doxycycline as Hyclate…500gm
	Diary No. Date of R& I & fee	Dy.No 28795 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Farmadox 50 Oral Powder of M/s ZS Biotech, Lahore. (Reg. No. 113635)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter	
758.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avi-Asper-C Powder
	Composition	Each Kg Contains: **Vitamin C**…200gm **Aspirin**…67gm Potassium Chloride…3gm Sodium Citrate…7gm
	Diary No. Date of R& I & fee	Dy.No 28797 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antipyretic
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm: Decontrolled
	Me-too status	Cyper-C Water Soluble Powder of M/s Farm Aid Group, Haripur. (Reg. No. 088019)
	GMP status	
	Remarks of the Evaluator [X]	**General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
759.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Amantacol-Liquid
	Composition	Each L contains: Enrofloxacin…100gm **Amantadine**…40gm
	Diary No. Date of R& I & fee	Dy.No 29793 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibacterial, Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the 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.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
760.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Delta M 2.5% Liquid
	Composition	Each ml contains: Deltamethrin…25mg
	Diary No. Date of R& I & fee	Dy.No 28796 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	D-Methrin Solution of Ms Alina Combine Pharmaceutical (Pvt) Ltd. Karachi. (Reg. No. 052351)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:**

		• Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and 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.	
761.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Flostin-Liquid
	Composition	Each ml contains: Florfenicol…230mg Colistin Sulphate…0.5MIU
	Diary No. Date of R& I & fee	Dy.No 29794 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Coliflor Solution of Ms Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088091)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Colistin Sulphate from MIU to milligrams.
	Decision: Approved. The firm shall submit the following before issuance of registration letter • **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** • **latest GMP inspection report conducted within the period of last three years** • **conversion of Colistin Sulphate from MIU to grams**	
762.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Brocina-Liquid
	Composition	Each L contains: Bromhexine HCl…20gm Menthol…40gm
	Diary No. Date of R& I & fee	Dy.No 28792 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Minbro-400 Oral Liquid of Ms Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112362)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	

763.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Cyper 10-Liquid
	Composition	Each ml Contains: Cypermethrin…100mg
	Diary No. Date of R& I & fee	Dy.No 28801 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Evidence of applied formulation/drug, as **Oral Liquid**, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report (conducted within the period of last three years).** • **Evidence of applied formulation/drug, as Oral Liquid, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
764.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Tilcosine-Liquid
	Composition	Each ml Contains: Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 28804 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 1000ml: Decontrolled
	Me-too status	Nutil Oral Liquid of M/s Shine Laboratories, Gujjar Khan. (Reg. No. 099382)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
765.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Tri-Ox Liquid
	Composition	Each ml contains: Triclabendazole…85mg Oxfendazole…22.65mg

	Diary No. Date of R& I & fee	Dy.No 28803 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Oscar Drench of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 088116)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
766.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Avibro Gold Liquid
	Composition	Each L contains: Bromhexine HCl…100gm
	Diary No. Date of R& I & fee	Dy.No 28802 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	ET Bromhexine Oral Liquid of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 112312)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
767.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Ecodin Liquid
	Composition	Each L contains: Enrofloxacin…100gm Colistin Sulphate…500MIU Bromhexine…40gm **Amantadine**…5gm
	Diary No. Date of R& I & fee	Dy.No 28805 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Antibiotic, Antiviral, Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	

	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Colistin Sulphate from MIU to gram. • Clarification regarding applied formulation is required since Enrofloxacin…100gm, Colistin Sulphate…500MIU, **Bromhexine…40gm and Amantadine…5gm/** Litre is mentioned on form 5 while Enrofloxacin…100gm, Colistin Sulphate…500MIU, **Bromhexine…5gm and Amantadine…40gm**/ Litre is mentioned on cover letter; and provide accordingly evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
768.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Flucina-20 Liquid
	Composition	Each ml contains: Florfenicol…200mg
	Diary No. Date of R& I & fee	Dy.No 31827 dated 30-11-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	I-Enicol Solution of Ms International Pharma Labs. Lahore. (Reg. No. 112298)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
769.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Cinazan Liquid
	Composition	Each L contains: Oxyclozanide…30gm Levamisole HCl…15gm
	Diary No. Date of R& I & fee	Dy.No 28790 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Dewormer
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Nilfar Oral Liquid of Ms Izfaar Pharmaceutical Industries, Lahore. (Reg. No. 095634)
	GMP status	

	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
770.	Name and address of manufacturer / Applicant	M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura.
	Brand Name +Dosage Form + Strength	Cinazan Gold Liquid
	Composition	Each L contains: Oxyclozanide…60gm Levamisole HCl…30gm
	Diary No. Date of R& I & fee	Dy.No 28791 dated 29-10-2020 Rs.20,000/- dated 29-10-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Nawazan DS Suspension of Ms Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 101445)
	GMP status	
	Remarks of the Evaluator [X]	**General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
771.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Restil-C Powder
	Composition	Each 100gm Contains: **Paracetamol**…2gm Ascorbic Acid…20gm Calcium Carbonate…4.5gm Magnesium Sulphate…3.5gm Potassium Chloride…4gm
	Diary No. Date of R& I & fee	Dy.No 34525 dated 28-12-2020 Rs.20,000/- dated 28-12-2020
	Pharmacological Group	Analgesic, Antipyretic, Vitamin and mineral supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1Kg: Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Oral Powder (General) section** confirmed vide letter No. F. 1-51/2004-Lic dated 07-02-2014. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).

	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
772.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Oxyriq-5 Injection 50ml
	Composition	Each ml contains: Oxytetracycline as HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 34599 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Levamycin-5% Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113403)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
773.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Imidobar 50ml Injection
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 34602 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Himido Injection (50ml) of M/s Hilton Pharma (Pvt) Ltd., Karachi. (Reg. No. 103945)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
774.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Diminariq Injection 50ml
	Composition	Each ml Contains: Diminazine Aceturate…105mg Antipyrine…131mg
	Diary No. Date of R& I & fee	Dy.No 34604 dated 29-12-2020 Rs.20,000/- dated 29-12-2020

	Pharmacological Group	Antipyretic, Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Durazene Easy Injection (50ml) of Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074017)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Deferred for review by expert working group for veterinary drugs.	
775.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Cgtbar Injection
	Composition	Each 100ml Contains: Gentamycin Sulphate…5gm Colistin Sulphate…60MIU Tylosin Tartrate…10gm
	Diary No. Date of R& I & fee	Dy.No 34600 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic/Antimicrobial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: As per SRO
	Me-too status	Gentyle+C Injection (100ml) of Ms Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080723)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	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 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
776.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Enrobar-20 Injection 50ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 34605 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic/Antimicrobial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Ceriflox 20% Injection (50ml) of Ms Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058940)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:**

		• Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
777.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Atrobar Injection
	Composition	Each ml Contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 34609 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Atrovet Injection (50ml) of Ms Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 034577)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
778.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Aderiq Injection 50ml
	Composition	Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 34606 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	3-Vitz Injection (50ml) of Ms Epoch Pharmaceuticals, Karachi. (Reg. No. 069614)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
779.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore

	Brand Name +Dosage Form + Strength	Aderiq Injection 100ml
	Composition	Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 34607 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: As per SRO
	Me-too status	3-Vitz Injection (100ml) of Ms Epoch Pharmaceuticals, Karachi. (Reg. No. 069614)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
780.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Loxibar Injection
	Composition	Each ml Contains: Flunixin Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 34601 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Loxin Injection (50ml) of Ms Selmore Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 035098)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg** **Firm shall submit fee of Rs. 30,000/- for correction in formulation and product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021; and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.**	
781.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Gentariq-10 Injection
	Composition	Each ml Contains: Gentamycin Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 34597 dated 29-12-2020 Rs.20,000/- dated 29-12-2020

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: As per SRO
	Me-too status	Genta-10 % Injection (100ml) of Ms Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 046547)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
782.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Pflox Oral Liquid
	Composition	Each 100ml Contains: Pefloxacin Methanesulfonate…13.960gm eq. to Pefloxacine Base…10gm
	Diary No. Date of R& I & fee	Dy.No 34595 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml; As per SRO
	Me-too status	Cipsin Oral Liquid of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh (Reg. No. 112363)
	GMP status	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
783.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Floxa-BC Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin…10gm Bromhexine HCl…0.5gm Colistin Sulphate…55 MIU
	Diary No. Date of R& I & fee	Dy.No 34598 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; As per SRO
	Me-too status	Enro CB Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 074083)
	GMP status	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.

	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Colistin Sulphate from MIU to grams.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **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** • **latest GMP inspection report conducted within the period of last three years** • **conversion of Colistin Sulphate from MIU to grams.**	
784.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Oflox Oral Liquid
	Composition	Each 100ml contains: Ofloxacin…10gm
	Diary No. Date of R& I & fee	Dy.No 34596 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 25000ml; As per SRO
	Me-too status	Oflobak Liquid of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063829)
	GMP status	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
785.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Iverbar Drench
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 34603 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; As per SRO
	Me-too status	Ivotek Drench 1% of M/s Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063601)
	GMP status	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
786.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore

	Brand Name +Dosage Form + Strength	Curebar Oral Suspension
	Composition	Each ml contains: Sulphadiazine…35.50mg Sulphadimidine…28.40mg Neomycin Sulphate…1.80mg Hyoscine Methylbromide…0.04mg Pectin…7.10mg Kaolin …103.30mg Vitamin B1…0.15mg Vitamin B2…0.22mg
	Diary No. Date of R& I & fee	Dy.No 34610 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Antibiotic, Antispasmodic and Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; As per SRO
	Me-too status	Scour-X Oral Suspension of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 029661)
	GMP status	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
787.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Diubenz Powder
	Composition	Each Kg Powder Contains: Sodium Benzoate…500gm Ethanol Beta Amino Phosphoric Acid…100gm Vitamin A…10,000,000 IU Vitamin E…2500mg Vitamin K3…1000mg Vitamin C…2500mg
	Diary No. Date of R& I & fee	Dy.No 34608 dated 29-12-2020 Rs.20,000/- dated 29-12-2020
	Pharmacological Group	Vitamin, growth promoter
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Diurizone Powder of M/s Mylab (Pvt) Ltd., Bahawalpur (Reg. No. 073908)
	GMP status	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance.
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • Provide conversion of Vitamin A from IU to milligrams.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **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** • **latest GMP inspection report conducted within the period of last three years** • **conversion of Vitamin A from IU to milligrams.**	

788.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Cypervetz Oral Liquid
	Composition	Each ml contains: Cypermethrin…10%
	Diary No. Date of R& I & fee	Dy.No 32479 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Ectoparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 500ml,1000ml: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Shortcomings:** • Clarification regarding dosage form is required since both "**oral liquid**" and "**for external use**" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide approval of relevant manufacturing facility.
	Decision: Deferred for following: • **Clarification regarding dosage form is required since both "oral liquid" and "for external use" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **approval of relevant manufacturing facility.**	
789.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Ivervet Oral Liquid
	Composition	Each ml Contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 32483 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml,1Liter, 5 Liter: Decontrolled
	Me-too status	Mecrold Drench of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109039)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Liquid (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
790.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Levovet Oral Liquid
	Composition	Each ml contains: Levamisole HCl…1.5% Cobalt Sulphate Heptahydrate…0.382%
	Diary No. Date of R& I & fee	Dy.No 32475 dated 07-12-2020 Rs.20,000/- dated 07-12-2020

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Nilverm Plus Drench of M/s Saitex Pharmaceutical Karachi (Reg. No.017951)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Liquid (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
791.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Linc S Vet Injection 50ml
	Composition	Each ml contains: Lincomycin as HCl…50mg Spectinomycin as Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 32478 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Linco-S Injection (50ml) of M/s Jfrin Pharmaceuticals, Karachi (Reg. No. 043248)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
792.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Linc S Vet Injection 100ml
	Composition	Each ml contains: Lincomycin as HCl…50mg Spectinomycin as Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 32477 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Linco-S Injection (100ml) of M/s Jfrin Pharmaceuticals, Karachi (Reg. No. 043248)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.

	Decision: Approved. 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.	
793.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Iversulone Injection for 10ml
	Composition	Each ml Contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 32473 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Elvomec Injection (10ml) of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 106658)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
794.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Iversulone Injection for 100ml
	Composition	Each ml Contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 324734 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Elvomec Injection (100ml) of M/s Elko Organization (Pvt.) Ltd, Karachi. (Reg. No. 106660)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
795.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Oxy-K LA Injection 50ml
	Composition	Each ml Contains: Oxytetracycline…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 32484 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Antibacterial/ Anti-inflammatory

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Pro Cycline Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111328)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
796.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Albavetz Oral Powder
	Composition	Each gm contains: Albendazole…200mg
	Diary No. Date of R& I & fee	Dy.No 32476 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, 30gm, 50gm, 100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Zoben 20 Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043285)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. 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.	
797.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Metrifonvet Oral Powder
	Composition	Each gm contains: Trichlorphone (Metrifonate)…960mg
	Diary No. Date of R& I & fee	Dy.No 32482 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 100gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Ectofon Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 041295)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.	
798.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.

	Brand Name +Dosage Form + Strength	Vetz-ADE-M Granular Powder
	Composition	Each Kg Contains: Vitamin A…0.5 MIU Vitamin D…0.08 MIU Vitamin E…0.3gm Calcium…225gm Phosphorous…120gm Magnesium…25gm Sodium…20gm Iron as Ferrous…1gm Zinc…3gm Manganese…2gm Copper…0.6gm Cobalt…0.01gm Iodine…0.02gm Selenium…0.003gm
	Diary No. Date of R& I & fee	Dy.No 32480 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Multivitamin and minerals
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm,20gm, 30gm, 50gm, 100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	ADE Minerals of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 035063) **Could not be confirmed**
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of testing facility.
	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.** • **Confirmation of testing facility** • **Completion of salt forms**	
799.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Deltavetz Oral Liquid
	Composition	Each ml Contains: Deltamethrin…25mg
	Diary No. Date of R& I & fee	Dy.No 32481 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Ectoparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 500ml,1000ml: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Shortcomings:** • Clarification regarding dosage form is required since both "**oral liquid**" and "**for external use**" are mentioned on

		form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide approval of relevant manufacturing facility.
	Decision: Deferred for following: • **Clarification regarding dosage form is required since both "oral liquid" and "for external use" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **approval of relevant manufacturing facility.**	
800.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	N-Chlor Powder
	Composition	Each Kg Contains: Chlortetracycline HCl…160gm Neomycin Sulphate…140gm Colistin Sulphate…8gm
	Diary No. Date of R& I & fee	Dy.No 33438 dated 16-12-2020 Rs.20,000/- dated 09-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **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 evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
801.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Amprovet Powder
	Composition	Each 100gm Contains: Amprolium HCl…30gm
	Diary No. Date of R& I & fee	Dy.No 32721 dated 09-12-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Amprobak-30 Water Soluble Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 063816)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
802.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Repto Powder

	Composition	Each gm contains: **Chlortetracycline HCl**…200mg **Neomycin Sulphate**…60mg **Colistin Sulphate**…10mg **Streptomycin Sulphate**…20mg
	Diary No. Date of R& I & fee	Dy.No 33436 dated 16-12-2020 Rs.20,000/- dated 09-12-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Streptochlor Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080738)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
803.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Cedox powder
	Composition	Each 1000gm contains: Tylosin Tartrate …100gm Doxycycline HCl …200gm Bromhexine HCl…5gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 33435 dated 16-12-2020 Rs.20,000/- dated 09-12-2020
	Pharmacological Group	Antibacterial/ Anti-viral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Tetravetz Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 079297) **Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **Shortcomings:** • Provide conversion of Colistin Sulphate from MIU to gram • 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: • **conversion of Colistin Sulphate from MIU to gram** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
804.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	NCS Powder
	Composition	Each gm contains: Neomycin Sulphate…60mg Chlortetracycline HCl…200mg Streptomycin Sulphate…20mg

	Diary No. Date of R& I & fee	Dy.No 32029 dated 02-12-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	NC Strep Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 079149)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
805.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Tetol Powder
	Composition	Each gm Contains: Chlortetracycline HCl …80mg Neomycin Sulphate …70mg Colistin Sulphate…4mg
	Diary No. Date of R& I & fee	Dy.No 32028 dated 02-12-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Striker Water Soluble Powder of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 078314)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
806.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Do-Flush Powder
	Composition	Each 100gm contains: Methenamine Mandelate…90gm Vitamin-B1…700mg Vitamin-C…100mg Sorbitol…5gm
	Diary No. Date of R& I & fee	Dy.No 33865 dated 21-12-2020 Rs.20,000/- dated 16-12-2020
	Pharmacological Group	**Diuretic and Detoxificant**
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Vety-Flush Powder of M/s Vety-Care Islamabad (Reg. No. 019938)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **Shortcomings:** • Pharmacological group mentioned in the form-5 is not correct. The firm shall submit fee of Rs. 7500/- for

		correction/pre-approval change in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- /- for correction/pre-approval change in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
807.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Etholium Powder
	Composition	Each gm contains: Amprolium HCl…200gm Ethopabate…20mg
	Diary No. Date of R& I & fee	Dy.No 32030 dated 02-12-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Ethoprol Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049617)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
808.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Oxoline Liquid
	Composition	Each 1000ml contains: Oxolinic Acid…100gm
	Diary No. Date of R& I & fee	Dy.No 32722 dated 09-12-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5Litre, 5Liter, 10Liter, 15Litre, 25Liter; Decontrolled
	Me-too status	Vety Oxol Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046668)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
809.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Toll-K Liquid
	Composition	Each 1000ml contains: Toltrazuril…25gm Vitamin K3…3gm
	Diary No. Date of R& I & fee	Dy.No 33864 dated 21-12-2020 Rs.20,000/- dated 16-12-2020
	Pharmacological Group	Anticoccidial/ Restorative
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5Litre, 5Liter, 10Liter, 15Litre, 20Liter, 25Liter; Decontrolled

	Me-too status	Tetzole Oral Liquid of M/s Ras Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 097953)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
810.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	N-Flox Solution
	Composition	Each Liter contains: Enrofloxacin…100g N-Acetyl-L-Cysteine…186g Propylene Glycol…100g Benzyl Alcohol…20g
	Diary No. Date of R& I & fee	Dy.No 33863 dated 21-12-2020 Rs.20,000/- dated 16-12-2020
	Pharmacological Group	Antibacterial/ Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5Litre, 5Liter, 10Liter, 15Litre, 20Liter, 25Liter; Decontrolled
	Me-too status	Penprol Solution of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 063718)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML.
	Decision: Approved	
811.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Floxa-20 Powder
	Composition	Each 100gm contains: Enrofloxacin…20gm Colistin Sulphate…45 MIU
	Diary No. Date of R& I & fee	Dy.No 34458 dated 28-12-2020 Rs.20,000/- dated 28-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm,1000gm; Decontrolled
	Me-too status	Enromall-C Oral Powder of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan. (Reg. No. 049731)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016. **Shortcomings:** • Provide conversion of Colistin Sulphate from MIU to grams
	Decision: Approved. 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 and conversion of Colistin Sulphate from MIU to grams before issuance of registration letter.	
812.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Floxa-10 Powder

	Composition	Each 100gm contains: Enrofloxacin…10gm
	Diary No. Date of R& I & fee	Dy.No 34459 dated 28-12-2020 Rs.20,000/- dated 28-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm; Decontrolled
	Me-too status	Vety-Enrox 10% Powder of M/s Vety-Care Pharma Islamabad (Reg. No. 025787)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Approved. 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 and before issuance of registration letter.	
813.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Maxicol Solution
	Composition	Each ml contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 31896 dated 01-12-2020 Rs.20,000/- dated 30-11-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 500ml, 1000ml, 5000ml: Decontrolled
	Me-too status	Thiafen Oral Liquid of M/s Farm Aid Group, Haripur. (Reg. No. 102204)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012.
	Decision: Approved. 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 and before issuance of registration letter.	
814.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Incol Injection 100ml
	Composition	Each 100ml contains: Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy.No 33572 dated 17-12-2020 Rs.20,000/- dated 17-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Coli 50 Injection (100ml) of M/s Attabak Pharmaceutical Islamabad (Reg. No. 058898)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	**neral) Section (Veterinary)** confirmed vide panel inspection tion conducted on 12-04-2021 & 15-04-2021 for renewal of f Colistin Sulphate from MIU to grams.(1mg=19000IU)

	Decision: Approved. 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 and before issuance of registration letter.	
815.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bio-E-Floxacin 10% Injection 10ml
	Composition	Each ml Contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 34335 dated 24-12-2020 Rs.20,000/- dated 24-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Encure-10 Injection (10ml) of M/s Nawan Labs Karachi (Reg. No. 020803)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. 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 and before issuance of registration letter.	
816.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Trimdiazine Injection
	Composition	Ecah ml Contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No 33778 dated 14-12-2020 Rs.20,000/- dated 14-12-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Tribactral Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 029613)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid injectable (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of DML renewal
	Decision: Approved. 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 and before issuance of registration letter.	
817.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Amantaflu-98 Oral Powder
	Composition	Each Kg Contains: **Amantadine HCl**…0.980Kg
	Diary No. Date of R& I & fee	Dy.No 34446 dated 28-12-2020 Rs.20,000/- dated 28-12-2020
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100gm, 500gm, 1000gm, and 2500gm; Decontrolled
	Me-too status	Menta Shell Oral Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad (Reg. No. 101968)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Powder (antibiotic)** and **Veterinary oral Powder (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
818.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Tylohawk-98 Oral Powder
	Composition	Each Kg Contains: Tylosin Tartrate…0.980Kg
	Diary No. Date of R& I & fee	Dy.No 33721 dated 18-12-2020 Rs.20,000/- dated 18-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, and 2500gm; Decontrolled
	Me-too status	Tylo Tartrate-98 Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113431)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Powder (antibiotic)** and **Veterinary oral Powder (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
819.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Bovimast Intramammary Suspension
	Composition	Each 10gm Syringe Contains: Alpha-Tocopherol Acetate (Vitamin E Acetate) …120mg Retinol Palmitate (Vitamin A Concentrate) …58.83mg (eq. to 100,000 IU) Chymotrypsin…2400 FIP-U Trypsin…240 FIP-U Papain…6 FIP-U
	Diary No. Date of R& I & fee	Dy.No 33288 dated 15-12-2020 Rs.20,000/- dated 15-12-2020
	Pharmacological Group	Proteolytic Enzymes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20 x 10gm Syringes: Decontrolled
	Me-too status	Masti Veyxym ® Suspension for Intramammary of M/s Mustafa Brothers, Faisalabad (Reg. No. 080766)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Sterile liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. 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 and before issuance of registration letter.	

820.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Mastiwork DC Intramammary Suspension
	Composition	Each 3gm syringe contains: Cephalonium as Dihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 33289 dated 15-12-2020 Rs.20,000/- dated 15-12-2020
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	20 x 3gm Syringes: Decontrolled
	Me-too status	Cepravin TM Dry Cow Intramammary of M/s ICI Pakistan Ltd Karachi (Reg. No.020133)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Sterile liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. 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 and before issuance of registration letter.	
821.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Cephicure 500mg Intrauterine Suspension
	Composition	Each 19.5gm Syringe Contains: Cephapirin as Benzathine…500mg
	Diary No. Date of R& I & fee	Dy.No 33290 dated 15-12-2020 Rs.20,000/- dated 15-12-2020
	Pharmacological Group	Antibacterial/ Anti-infective/ Antiseptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10 x 19.5gm Syringes: Decontrolled
	Me-too status	Metricure white oily homogenous Intra-Uterine suspension of M/s ICI Pakistan Ltd Karachi (Reg. No. 078355) **Could not be confirmed in the applied strength**
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	**Shortcomings:** • **Approval of Relevant section** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**
	Decision: Deferred for following: • **approval of relevant manufacturing facility** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

Case no. 02 Registration applications of newly granted DML or New section (Veterinary)

a. New DML /section

I. M/s Farm Aid Pharmaceuticals, Haripur. **(Additional Section)**

CLB in its 286th meeting held on 11th May, 2022 has considered and approved the following additional section.

1. **Liquid Injection (General/ Antibiotic)-Veterinary**

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

Section	Previously considered applications in M-321		No. of balance Molecules
	No. of Molecules	No. of Products	

Liquid Injection (General/ Antibiotic)-Veterinary	05	35	05

Now, following applications of the firm have been received and are presented below for consideration, against the available balance for priority consideration.

Liquid Injection (General/ Antibiotic)-Veterinary
(05 Molecules/ 25 products)

822.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	M Vit injection 250ml
	Composition	Each 100ml contains: L-Carnitine…500mg Pyridoxine HCl…15mg L-Arginine…240mg L-Citruline …120mg Glycine…150mg Aspartic Acid …150mg Fructose...5000mg Thiotic Acid...20mg DL-Acetylmethionine ...2000mg L-Ornithine...120mg L-Lysine ...50mg Taurine...150mg Glutamic Acid ...150mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 22369 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Multivitamins and Amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Multimino-V Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	**New Section**
	Remarks of the Evaluator [x]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Deferred for confirmation of relevant manufacturing facility(LVP) and testing facility	
823.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	M Vit injection 100ml
	Composition	Each 100ml contains: L-Carnitine…500mg Pyridoxine HCl…15mg L-Arginine…240mg L-Citruline …120mg Glycine…150mg Aspartic Acid …150mg Fructose...5000mg Thiotic Acid...20mg DL-Acetylmethionine ...2000mg L-Ornithine...120mg L-Lysine ...50mg Taurine...150mg Glutamic Acid ...150mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 22367 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Multivitamins and Amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications

	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Multimino-V Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Deferred for confirmation of testing facility	
824.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	M Vit injection 500ml
	Composition	Each 100ml contains: L-Carnitine…500mg Pyridoxine HCl…15mg L-Arginine…240mg L-Citruline …120mg Glycine…150mg Aspartic Acid …150mg Fructose...5000mg Thiotic Acid...20mg DL-Acetylmethionine ...2000mg L-Ornithine...120mg L-Lysine ...50mg Taurine...150mg Glutamic Acid ...150mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 22367 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Multivitamins and Amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	Multimino-V Injection (500ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Deferred for confirmation of relevant manufacturing facility(LVP) and testing facility	
825.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vit 1000 injection 10ml
	Composition	Each ml contains: Vitamin -A…100,000-I.U Vitamin -D3…40,000-I.U Vitamin-E…40mg
	Diary No. Date of R& I & fee	Dy.No 22373 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Vitamins Supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Adeka Injection (10ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022 • Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. **Vitamin A** (3333.3 IU = 1mg)

		Vitamin D3 (40,000 IU = 1mg)
	Decision: Approved	
826.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vit 1000 injection 50ml
	Composition	Each ml contains: Vitamin -A…100,000-I.U Vitamin -D3…40,000-I.U Vitamin-E…40mg
	Diary No. Date of R& I & fee	Dy.No 22374 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Vitamins Supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Adeka Injection (50ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022 • Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. **Vitamin A** (3333.3 IU = 1mg) **Vitamin D3** (40,000 IU = 1mg)
	Decision: Approved	
827.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vit 1000 injection 100ml
	Composition	Each ml contains: Vitamin -A…100,000-I.U Vitamin -D3…40,000-I.U Vitamin-E…40mg
	Diary No. Date of R& I & fee	Dy.No 22375 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Vitamins Supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Adeka Injection (100ml) of M/s A & K Pharmaceutical, Faisalabad. (Reg. No. 075792)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022 • Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. **Vitamin A** (3333.3 IU = 1mg) **Vitamin D3** (40,000 IU = 1mg)
	Decision: Approved	
828.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vit 500 injection 10ml
	Composition	Each ml contains: Vitamin -A…500,000-IU Vitamin -D3…75,000-IU Vitamin-E…50mg
	Diary No. Date of R& I & fee	Dy.No 22370 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Vitamins Supplement

	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Duravit AD3E Injection (10ml) of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 074018)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022 • Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. **Vitamin A** (3333.3 IU = 1mg) **Vitamin D3** (40,000 IU = 1mg)
	Decision: Approved	
829.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vit 500 injection 50ml
	Composition	Each ml contains: Vitamin -A…500,000-IU Vitamin -D3…75,000-IU Vitamin-E…50mg
	Diary No. Date of R& I & fee	Dy.No 22371 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Vitamins Supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Duravit AD3E Injection (50ml) of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 074018)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022 • Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. **Vitamin A** (3333.3 IU = 1mg) **Vitamin D3** (40,000 IU = 1mg)
	Decision: Approved	
830.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vit 500 injection 100ml
	Composition	Each ml contains: Vitamin -A…500,000-IU Vitamin -D3…75,000-IU Vitamin-E…50mg
	Diary No. Date of R& I & fee	Dy.No 22372 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Vitamins Supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Duravit AD3E Injection (100ml) of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 074018)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022 • Provided conversion of Vitamin A and Vitamin D3 from IU to milligrams. **Vitamin A** (3333.3 IU = 1mg) **Vitamin D3** (40,000 IU = 1mg)
	Decision: Approved	

831.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F Dine 33.3 injection 250ml
	Composition	Each ml contains: Sulfadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 22365 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Sulphadimidine Sodium Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 058714)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Deferred for confirmation of relevant manufacturing facility(LVP)	
832.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F Dine 33.3 injection 500ml
	Composition	Each ml contains: Sulfadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 22366 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	Sulphadimidine Sodium Injection (500ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 058714)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Deferred for confirmation of relevant manufacturing facility(LVP)	
833.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F Dine 33.3 injection 100ml
	Composition	Each ml contains: Sulfadimidine Sodium…333mg
	Diary No. Date of R& I & fee	Dy.No 22364 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Sulphadimidine Sodium Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 058714)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
834.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fumin 5% Injection 10ml
	Composition	Each ml contains: Flunixin Meglumin…50mg

	Diary No. Date of R& I & fee	Dy.No 22358 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Loxicon Injection (10ml) of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir (Reg. No.058704)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg** **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.**	
835.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fumin 5% Injection 50ml
	Composition	Each ml contains: Flunixin Meglumin…50mg
	Diary No. Date of R& I & fee	Dy.No 22359 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Loxicon Injection (50ml) of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir (Reg. No.058704)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg** **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.**	
836.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fumin 5% Injection 100ml
	Composition	Each ml contains: Flunixin Meglumin…50mg
	Diary No. Date of R& I & fee	Dy.No 22360 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Loxicon Injection (100ml) of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir (Reg. No.058704)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….50 mg**	

	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.	
837.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fumin 8.3% Injection 10ml
	Composition	Each ml contains: Flunixin Meglumin…83mg
	Diary No. Date of R& I & fee	Dy.No 22361 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Nixsym Injection (10ml) of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….83 mg** **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.**	
838.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fumin 8.3% Injection 100ml
	Composition	Each ml contains: Flunixin Meglumin…83mg
	Diary No. Date of R& I & fee	Dy.No 22363 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Nixsym Injection (100ml) of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….83 mg** **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.**	
839.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Fumin 8.3% Injection 50ml
	Composition	Each ml contains: Flunixin Meglumin…83mg
	Diary No. Date of R& I & fee	Dy.No 22362 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled

	Me-too status	Nixsym Injection (50ml) of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved with following label claim: **Each ml Contains:** **Flunixin as Meglumine….83 mg** **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.**	
840.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 110 Injection 10ml
	Composition	Each 100ml contains: Ivermectin…1g Clorsulon…10g
	Diary No. Date of R& I & fee	Dy.No 22351 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Actimec Plus Injection (10ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
841.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 110 Injection 50ml
	Composition	Each 100ml contains: Ivermectin…1g Clorsulon…10g
	Diary No. Date of R& I & fee	Dy.No 22352 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Actimec Plus Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
842.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 110 Injection 100ml
	Composition	Each 100ml contains: Ivermectin…1g Clorsulon…10g
	Diary No. Date of R& I & fee	Dy.No 22353 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications

	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Actimec Plus Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
843.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 210 Injection 10ml
	Composition	Each 100ml contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 22354 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ivobak Super Injection (10ml) of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 063825)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
844.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 210 Injection 50ml
	Composition	Each 100ml contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 22355 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ivobak Super Injection (50ml) of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 063825)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
845.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 210 Injection 100ml
	Composition	Each 100ml contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 22356 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ivobak Super Injection (100ml) of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 063825)
	GMP status	**New Section**

	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	
846.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Mecsul 2010 Injection 50ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…10mg
	Diary No. Date of R& I & fee	Dy.No 22357 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ivoclor Injection (50ml) of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 078244)
	GMP status	**New Section**
	Remarks of the Evaluator [X]	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision: Approved	

b. Deferred Cases

847.	Name and address of manufacturer / Applicant	M/s Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	OxyJet-200 Injection (50ml)
	Composition	Each ml contains: Oxytetracycline as dihydrate…200 mg Lignocaine HCl…20 mg
	Diary No. Date of R& I & fee	Dy no: 34786, 30-12-2020, Rs. 20,000/-, 29-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	50 ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Oxy-L20 Injection (50ml) (Reg.#034547)
	GMP status	Liquid Injection Vial (General) Veterinary section –New vide letter No F.1-36/2006- Lic(Vol-III) Dated 12-03-2021 on the basis of inspection conducted on Date 08-10-2020 recommending grant of injection general section
	Remarks of the Evaluator [X]	Above mentioned formulation contains Oxytetracycline HCl whereas this formulation contains Oxytetracycline as dihydrate. Firm has applied these products as same molecule.
	Decision of 308th meeting of RB: Deferred for confirmation of formulation in Reference Regulatory Authority	
	Firm's response: The firm has submitted that there was typographical error in formulation mentioned in minutes of 308th meeting of the Registration Board on DRAP end. The firm has also submitted copy of receiving of their initial application, submitted in DRAP, in support of their claim. Now, the firm has revised their request as mentioned below: Each ml contains: Oxytetracycline as Hydrochloride…200 mg Lignocaine HCl…20 mg Applied pack size: **100ml** Me-too status: Oxywim Injection (100ml) M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 088617)	

	Firm has submitted fee Rs. 7,500/- vide slip No. 71135193414 and differential fee of Rs.22,500/- vide slip No. 293402885 for pre-approval revision of formulation and pack size as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
	Decision: Approved with pack size of 100ml and following label claim **Each ml contains:** **Oxytetracycline as Hydrochloride…200 mg** **Lignocaine HCl…20 mg**	

Case no. 03 Registration applications of categories to be considered on priority

c. Export facilitation

Deputy Director PRV/EFD vide letter No.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision, **M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore** has submitted following applications for priority consideration/ evaluation in lieu of export facilitation, submitted before the Board for its consideration please:

848.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mucosta 100ml Injection
	Composition	Each ml Contains: Enrofloxacin…10% Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 30037 dated 24-10-2022 Rs.30,000/- dated 19-10-2022
	Pharmacological Group	Antibiotic/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Bromoflox Injection (100ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 075603)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection dated 24-01-2020
	Remarks of the Evaluator [X]	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved	
849.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mucosta 50ml Injection
	Composition	Each ml Contains: Enrofloxacin…10% Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 30036 dated 24-10-2022 Rs.30,000/- dated 19-10-2022
	Pharmacological Group	Antibiotic/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Bromoflox Injection (50ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 075603)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection dated 24-01-2020
	Remarks of the Evaluator [X]	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved	
850.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.

	Brand Name +Dosage Form + Strength	Mucosta 10ml Injection
	Composition	Each ml Contains: Enrofloxacin…10% Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 30035 dated 24-10-2022 Rs.30,000/- dated 19-10-2022
	Pharmacological Group	Antibiotic/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Bromoflox Injection (10ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 075603)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection dated 24-01-2020
	Remarks of the Evaluator X	Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved	

Deputy Director PRV/EFD vide letter No.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision, **M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore** has submitted following applications for priority consideration/ evaluation in lieu of export facilitation, submitted before the Board for its consideration please:

851.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Actibol Injection 50ml
	Composition	Each ml Contains: Cyanocobalamin…500mcg Sodium Selenite…1mg Adenosine Triphosphate Tetra Sodium Dihydrate Salt…1mg Potassium Aspartate Semihydrate…10mg Magnesium Aspartate Tetraydrate…15mg
	Diary No. Date of R& I & fee	Dy.No 705 dated 09-01-2023 Rs.30,000/- dated 06-12-2022
	Pharmacological Group	Vitamins with minerals
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Biosal Injection (50ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator X	• **Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary)** section confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved	
852.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Actibol Injection 10ml
	Composition	Each ml Contains: Cyanocobalamin…500mcg Sodium Selenite…1mg

		Adenosine Triphosphate Tetra Sodium Dihydrate Salt…1mg Potassium Aspartate Semihydrate…10mg Magnesium Aspartate Tetraydrate…15mg
	Diary No. Date of R& I & fee	Dy.No 704 dated 09-01-2023 Rs.30,000/- dated 06-12-2022
	Pharmacological Group	Vitamins with minerals
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Biosal Injection (10ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [x]	• **Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022.
	Decision: Approved	

Case no. 04 Registration applications of import cases

a. New Cases (Veterinary)

853.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18339 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Ceftiofur S Suspension for Injection
	Composition	Each 100ml Contains: Ceftiofur HCl…5gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Ceptifi Veterinary Injectable Suspension (100ml) of M/s Al-Asar Enterprises, Multan. (Reg. No. 094479)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1211/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin.

		Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the **scope of manufacturing operations of β-Lactam antibiotics (solution and suspension for injection)** **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd., Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted scanned copy **is expired now but valid upon submission.**
	Decision: Deferred for following • **confirmation of dedicated manufacturing facility** • **original valid legalized relevant GMP certificate**	
854.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18336 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Genta 10 I Injection
	Composition	Each 100ml Contains: Gentamycin Sulphate…10gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	G-Gen 100 Injection (100ml) of M/s Grand Pharma (Pvt.) Ltd., Islamabad. (Reg. No. 111567)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1308/2019/QLT-CFS dated 26-12-2019 issued by Department of Animal Health,

		Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Originally Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Original legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission. • Provide original valid Legalized FSC since already submitted is expired now but valid upon submission
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **original valid Legalized FSC** • **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**	
855.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18331 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Amox Gen S Suspension
	Composition	Each 100ml contains: Amoxicillin Trihydrate…15gm Gentamycin Sulphate…4gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years

	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Pro-Mox Injection (100ml) of M/s Prix Pharmaceutica, Lahore. (Reg. No.102203)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1214/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of β-Lactam antibiotics (solution and suspension for injection) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd., Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted scanned copy is expired now but valid upon submission.
	Decision: Deferred for following • **confirmation of dedicated manufacturing facility** • **original valid legalized relevant GMP certificate**	
856.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18335 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Enro 10 I Injection
	Composition	Each 100ml Contains: Enrofloxacin…10gm
	Finished Product Specification	Inhouse

	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Enro-Pro 10 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113561)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1215/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission.
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **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**	
857.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18329 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020

	Brand Name +Dosage Form + Strength	Apa Marbo 10 I Injection
	Composition	Each 100ml contains: Marbofloxacin…10gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Marcin Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 088117)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1305/2019/QLT-CFS dated 26-12-2019 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission. • Provide original valid Legalized FSC since already submitted is expired now but valid upon submission
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **original valid Legalized FSC** • **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**	
858.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam

	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18334 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Clorprostinex Injection
	Composition	Each ml Contains: Cloprostenol Sodium 26.3mg Eq. To Cloprostenol…25mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Prostaglandin
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	N/A
	Me-too status	Ovuprost Injection (20ml) of M/s Ghazi Brothers, Karachi. (Reg. No.099427)
	Detail of certificates attached	➢ Originally Legalized FSC No. 459/2020/QLT-CFS dated 15-05-2020 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam; its **scope does not cover manufacturing operations of injectable Hormone.** **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide legalized original valid relevant GMP certificate since the scope of already submitted copy does not cover manufacturing operations of **injectable Hormone.** • Provide original valid Legalized FSC since already submitted is expired now but valid upon submission
	Decision: Deferred for following • **confirmation of relevant manufacturing facility** • **original valid legalized relevant GMP certificate** • **original valid Legalized FSC**	
859.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023..**

		Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18337 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Gentylo I Injection
	Composition	Each 100ml Contains: Gentamycin Sulphate…5gm Tylosin Tartrate…10gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Gtrise Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 112180)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1218/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission.
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **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**	

860.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18333 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Amox 15S Suspension
	Composition	Each 100ml contains: Amoxicillin Trihydrate…15gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Sinomox LA Suspension for Injection (100ml) of M/s Ghazi Brothers, Karachi. (Reg. No. 106781)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1216/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of β-Lactam antibiotics (solution and suspension for injection) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd., Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted scanned copy is expired now but valid upon submission.
	Decision: Deferred for following	

	• **confirmation of dedicated manufacturing facility** • **original valid legalized relevant GMP certificate**	
861.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18332 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Tylosin 20 I Injection
	Composition	Each 100ml contains: Tylosin Tartrate…20gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Tyrate-20% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 109934)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1212/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:**

		• Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission.
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **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**	
862.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18338 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	APA Ive I Injection
	Composition	Each 100ml contains: Ivermectin…1gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Endectocide
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Ivoron Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 112244)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1217/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.

	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission.
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **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**	
863.	Name and address of Applicant	M/s Vetynex Pharma, 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Vetynex Pharma, Address: 1.5 Km, Defense Road, Off Ferozpur Road, Kahna Nau-Lahore Validity: **16-12-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name and address of marketing authorization holder	M/s APA United Nano Technology Co., Ltd. Lot C2-4, Vl3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18330 Dated 27-07-2020
	Fee including differential fee	Rs : 1,00,000 Dated 27-07-2020
	Brand Name +Dosage Form + Strength	Apa Linco Spec I Injection
	Composition	Each 100ml contains: Lincomycin HCl…5gm Spectinomycin HCl…10gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics
	Shelf life	02 Years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Speclin Injection (100ml) of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 063892)
	Detail of certificates attached	➢ Originally Legalized FSC No. 1213/2021/QLT-CFS dated 22-11-2021 issued by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms Free sale status of applied product in country of origin. Validity: 02 years ➢ Scanned copy of Legalized GMP certificate certified by Department of Animal Health, Ministry of Agriculture and Rural Development, Socialist Republic of Vietnam confirms the scope of manufacturing operations of non β-Lactam antibiotics (solution for injection, solution, and powder for oral use) **Issued on:** 02-06-2017 **Validity**: 5 years ➢ Photocopy of legalized distribution agreement made on 02-12-2019 between M/s Vetynex Pharma, 1.5 Km, Defense

		Road, Off Ferozpur Road, Kahna Nau-Lahore and M/s APA United Nano Technology Co., Ltd. Lot C2-4, VL3 Street, Vinh Loc 2 Industrial Park, Voi La Hamlet, Long Hiep Commune, Ben Luc District, Long An Province, Vietnam.
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-B conditions. **Shortcomings:** • Provide original valid Legalized GMP since already submitted GMP certificate is expired now but valid upon submission.
	Decision: Approved. Firm shall submit following before issuance of registration letter. • **original valid Legalized GMP certificate.** • **fee of Rs. 30,000/- for correction/pre-approval change in product salt as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
864.	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad
	Detail of Drug Sale License	Name: M/s Mustafa Brothers Address: P-186-D, Peoples Colony No.1, District Faisalabad Date of issuance:15-09-2022 Validity: 21-06-2027 Status: License to sale Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Osmosis Nutrition Sdn. Bhd., 16014, Jalan Nilam 3, Bandar Nilai Utama, 71800 Nilai, Negeri Sembilan, Malaysia
	Name and address of marketing authorization holder	M/s Osmosis Nutrition Sdn. Bhd., 16014, Jalan Nilam 3, Bandar Nilai Utama, 71800 Nilai, Negeri Sembilan, Malaysia
	Name of exporting country	Malaysia
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 16318 Dated 08-07-2020
	Fee including differential fee	Rs : 100,000 Dated 08-07-2020
	Brand Name +Dosage Form + Strength	Lincocen 44 Premix Powder
	Composition	Each gram Contains: Lincomycin Hydrochloride eq. to Lincomycin…44mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	1Kg, 5Kg, 10Kg, 25Kg
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original Legalized COPP No. 0564HA/2018 dated 21-08-2018 issued by Drug Control Authority National Pharmaceutical Regulatory Division (NPRA), Ministry of Health Malaysia confirms GMP status of the manufacturer but **DOES NOT CONFIRM** free sale status of the product in the exporting country. Validity: 2 Years ➢ Original Legalized GMP certificate No. 793/18 issued on 02-08-2018 is **valid upon submission but expired now.** ➢ Original Legalized power of attorney dated 06-09-2018 to the applicant for the applied product.
	Remarks of the Evaluator [X]	**Shortcomings:** • Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country • Provide Original legalized valid COPP and GMP certificate since the already submitted original COPP and GMP certificate **are expired now but valid upon submission.**

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following • **Status of Free sale in exporting country, since as per COPP the applied product is not licensed to be placed on market for use in the exporting country** • **Original legalized valid COPP and GMP certificates** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
865.	Name and address of Applicant	M/s Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan.
	Detail of Drug Sale License	Name: M/s Huzaifa International Address: Commercial Area, Aziz Bhatti Town, Sargodha. Validity: **20-11-2019** Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Komipharm International Co., Ltd. 17 Gyeongje-ro, Siheung-Si, Gyeonggi-Do, South Korea
	Name and address of marketing authorization holder	M/s Komipharm International Co., Ltd. 17 Gyeongje-ro, Siheung-Si, Gyeonggi-Do, South Korea
	Name of exporting country	The Republic of Korea (South Korea)
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 32616 Dated 08-12-2020
	Fee including differential fee	Rs : 100,000 Dated 08-12-2020
	Brand Name +Dosage Form + Strength	Komidocarb Injection
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anti-parasitic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml, 100ml
	International availability	N/A
	Me-too status	Durazol Injection (10ml, 20ml, 50ml, 100ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 078204)
	Detail of certificates attached	➢ Originally legalized FSC certificate No. M2010391 issued by the Animal and plant Quarantine Agency, republic of Korea **DOES NOT CONFIRM** free sale status of the product in exporting country. ➢ Original legalized GMP certificate dated 06-04-2020 issued by the Animal and plant Quarantine Agency, republic of Korea ➢ Scanned copy of authorization letter dated 06-10-2020 between PLH and Applicant
	Remarks of the Evaluator [X]	Provided 06months accelerated and 36months real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Provide originally legalized FSC since the already submitted FSC states that *the applied product is registered and permitted to be freely sold in* ***overseas markets***.

		• In the finished product label the Urdu version of the following namely; (i) dosage; and (ii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following • **valid copy of DSL** • **originally legalized Free Sale Certificate** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
866.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: **14 April, 2020.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 20576 Dated 19-08-2020
	Fee including differential fee	Rs : 1,00,000 Dated 19-08-2020
	Brand Name +Dosage Form + Strength	Tylofarm- Water Soluble Powder
	Composition	Each 100gram Contains: Tylosin Tartrate…40,000,000 IU (50g)
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	1Kg, 5Kg, 10Kg, 25Kg
	International availability	N/A
	Me-too status	Tylo-50 Water Soluble Powder of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 063847)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 23-02-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. ➢ Original legalized Letter of Authorization dated 05-03-2020
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ 6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision: Deferred for following: • **valid copy of DSL** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986**	
867.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical

		Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: **14 April, 2020.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24241 Dated 17-09-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-09-2020
	Brand Name +Dosage Form + Strength	Gentamast F-Intramammary Suspension
	Composition	Each Gram Contains: Gentamicin Sulphate…10,000 IU (0.0167gm)
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	10gm
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➢ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator [X]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
	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.** • **valid copy of DSL** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986**	
868.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: **14 April, 2020.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria

	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 20575 Dated 19-08-2020
	Fee including differential fee	Rs : 1,00,000 Dated 19-08-2020
	Brand Name +Dosage Form + Strength	Cypermethrin Farma
	Composition	Each 100ml Contains: Cypermethrin…10gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides for topical use
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	1L, 5L, 10L
	International availability	N/A
	Me-too status	Cypercid Liquid of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 112138)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➢ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator [X]	• Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision: Deferred for following: • **valid copy of DSL** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986**	
869.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: **14 April, 2020.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 32615 Dated 08-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 08-12-2020
	Brand Name +Dosage Form + Strength	Permethrin Pharma Insecticide Shampoo
	Composition	Each 100ml Contains:

		Permethrin…1g
	Finished Product Specification	Inhouse
	Pharmacological Group	Pyrethrines
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	N/A
	Me-too status	Could not be confirmed
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➢ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator [X]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	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.** • **valid copy of DSL** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986**	
870.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 26418 Dated 07-10-2020
	Fee including differential fee	Rs : 1,00,000 Dated 07-10-2020
	Brand Name +Dosage Form + Strength	Bovicef 25mg/ml Injectable Suspension
	Composition	Each ml Contains: Cefquinome as Cefquinome Sulphate…25mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Cephalosporin antibiotic
	Shelf life	24 months
	Demanded Price	N/A

	Pack size	50ml
	International availability	N/A
	Me-too status	Cefanil Injection (50ml) of M/s Nawan Laboratories (Pvt.) Ltd, Karachi. (Reg. No. 081319)
	Detail of certificates attached	Originally legalized COPP No. (2014)150252297 dated 03/03/2020 certified by Bureau of Animal Husbandry & Veterinary of Shandong Province, China confirms the GMP status of the manufacturer as well as free sale status of the product in exporting country. **Copy of Authorization Letter dated** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [X]	**Shortcomings:** • The submitted photocopy of letter of Authorization (LOA) is **expired now, but valid upon submission,** Provide legalized valid original LOA • Provide both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life. • Confirmation of dedicated manufacturing facility.
	Decision: Deferred for following • **legalized valid original LOA** • **both accelerated and real time stability studies data of three batches as per zone IV-A conditions upto claimed shelf life.** • **Confirmation of dedicated manufacturing facility**	
871.	Name and address of Applicant	M/s Schiwo Pakistan, 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Schiwo Pakistan Address: 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan Date of validity: **26-08-2023.** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name and address of marketing authorization holder	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33650 Dated 17-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-12-2020
	Brand Name +Dosage Form + Strength	Asi-Tilmitrec
	Composition	Each 1000ml Contains: Tilmicosin Phosphate…250g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	100ml, 1Liter
	International availability	N/A
	Me-too status	Mili Tilmico 25 Oral Liquid of M/s Mili Vet Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 112231)

	Detail of certificates attached	Originally legalized FSC No. 1079/2019/QLT-CFS dated 26-09-2019 certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms the free sale status of the product in exporting country. Validity: 2 years Scanned copy of GMP certificate dated **26-12-2016** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam Scanned copy of Authorization Letter dated **14-06-2018**
	Remarks of the Evaluator [X]	➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-B conditions. **Shortcomings:** • The submitted Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Provide legalized valid original letter of Authorization (LOA) since already submitted is scanned copy.
	Decision: Approved. Firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate.** • **legalized valid original letter of Authorization (LOA)** • **Submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
872.	Name and address of Applicant	M/s Schiwo Pakistan, 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Schiwo Pakistan Address: 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan Date of validity: 26-08-2023. Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name and address of marketing authorization holder	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33651 Dated 17-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-12-2020
	Brand Name +Dosage Form + Strength	Asi-Dox 50
	Composition	Each 1Kg contains: Doxycycline Hyclate…500g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	100gm, 1Kg
	International availability	N/A

	Me-too status	Doxline 50 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 112322)
	Detail of certificates attached	Originally legalized FSC No. 1076/2019/QLT-CFS dated **26-09-2019** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms the free sale status of the product in exporting country. Validity: 2 years Scanned copy of GMP certificate dated **26-12-2016** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam Scanned copy of Authorization Letter dated **14-06-2018**
	Remarks of the Evaluator [X]	➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-B conditions. **Shortcomings:** • The submitted Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Provide legalized valid original letter of Authorization (LOA) since already submitted is scanned copy.
	Decision: Approved. Firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate.** • **legalized valid original letter of Authorization (LOA)**	
873.	Name and address of Applicant	M/s Schiwo Pakistan, 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan
	Detail of Drug Sale License	Name: M/s Schiwo Pakistan Address: 11-G, Shah Rukan-e-Alam Colony, Multan, Punjab, Pakistan Date of validity: 26-08-2023. Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name and address of marketing authorization holder	M/s Thinh A Trading and Manufacturing Veterinary Medicine Co. (ASIFAC), 220 Pharm The Hien Street, Ward 2, Distric 8, Ho Chi Minh City, Viet Nam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist.,Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33649 Dated 17-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 17-12-2020
	Brand Name +Dosage Form + Strength	Asi-Amox Max
	Composition	Each 1000g Contains: Amoxicillin Trihydrate…500g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	100gm, 1Kg
	International availability	N/A
	Me-too status	Amoxicilina 500 Karizoo of M/s Unicare Enterprises,

		Faisalabad. (Reg. No. 081302)
	Detail of certificates attached	Originally legalized FSC No. 1082/2019/QLT-CFS dated **26-09-2019** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms the free sale status of the product in exporting country. Validity: 2 years Scanned copy of GMP certificate dated **23-10-2017** certified by Ministry of Agriculture and Rural Development Department of Animal Health, Vietnam confirms GMP status for production lines of Beta- lactam in the form of powder for oral use Scanned copy of Authorization Letter dated **14-06-2018**
	Remarks of the Evaluator [X]	➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-B conditions. **Shortcomings:** • The submitted Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Provide legalized valid original letter of Authorization (LOA) since already submitted is scanned copy.
	Decision: Deferred for following: • **Confirmation of dedicated manufacturing facility** • **legalized valid original FSC.** • **legalized valid original GMP certificate.** • **legalized valid original letter of Authorization (LOA)**	
874.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zhummadian Huazhong Chia Tai. No.2019, Leshan Road, High Technology Development Zone, Zhumadian, Henan, China
	Name and address of marketing authorization holder	M/s Zhummadian Huazhong Chia Tai. No.2019, Leshan Road, High Technology Development Zone, Zhumadian, Henan, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24963 Dated 24-09-2020
	Fee including differential fee	**Rs : 50,000** Dated 23-09-2020
	Brand Name +Dosage Form + Strength	Tylomax 10% Premix
	Composition	Each Kg contains: Tylosin Phosphate…100gm
	Finished Product Specification	Chinese Pharmacopeia
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	Not provided
	Me-too status	Ty-Mix 10 Premix of M/s Breeze Pharma Islamabad. (Reg. No. 059160)

	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 201100B0/021525 issued by Animal Husbandry Bureau of Zhumadian City, Henan Province China Date of issuance: 02-04-2020 Validity: 01-04-2024 ➢ Original Legalized GMP Certificate No. (2019) GMP16018 issued by Bureau of Animal Husbandry, Henan Province China Date of issuance: 21-05-2019 Validity: 20-05-2024 ➢ Photocopy of Power of Attorney dated 12-03-2019 for the applied product
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee Rs. 50,000/- for registration of generic drug product. • The provided Letter of Authorization (LOA)/ sole agency certificate is copy**,** Provide legalized valid original LOA from product license holder.
	Decision: Deferred for following • **Differential fee Rs. 50,000/- for registration of generic drug product.** • **Original legalized valid Letter of Authorization (LOA)/ sole agency certificate from product license holder**	
875.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Richter Pharma, AG, Durisolstrabe 14, 4600 Wels, Austria
	Name and address of marketing authorization holder	M/s Richter Pharma, AG, Durisolstrabe 14, 4600 Wels, Austria.
	Name of exporting country	Austria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34336 Dated 24-12-2020
	Fee including differential fee	**Rs : 50,000** Dated 24-12-2020
	Brand Name +Dosage Form + Strength	Mitex Ear Drops (Cutaneous Suspension)
	Composition	Strength of Active Ingredient per unit dose: Miconazole Nitrate …23mg (eq. to 19.98mg of Miconazole) Prednisolone Acetate …5mg (Eq. to 4.48mg of prednisolone) Polymyxin B Sulphate …0.5293mg (Eq. to 5500 IU Polymyxin B Sulphate)
	Finished Product Specification	Inhouse
	Pharmacological Group	Corticosteroid, anti-infective
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	**Austria approved**
	Me-too status	N/A
	Detail of certificates attached	➢ Original Legalized COPP Certificate No. 12826569 issued by BASG/ AGES Traisengasse 5, A-1200 Wien confirms **GMP status of the manufacturer, and that the product is licensed to be placed on market but not actually on**

		the market in the exporting country. (since Austria acts as Reference Member State, the product is marketed only in Concerned Member State) Date of issuance: 04-03-2020 ➢ Scanned copy of Legalized Power of attorney provided.
	Remarks of the Evaluator [X]	06 months accelerated and **18 months** long term stability studies data as per zone-IV-A conditions provided **Shortcomings:** • Provide original Legalized Power of attorney/sole agency certificate**.**
	Decision: Defer for free sale status of applied produc in country of origin.	
876.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Lifecome Biochemistry Co., Ltd. No.19, Nanpu Ecological Indsutrial Park, Pucheng, Fujian, P.R.China
	Name and address of marketing authorization holder	M/s Lifecome Biochemistry Co., Ltd. No.19, Nanpu Ecological Indsutrial Park, Pucheng, Fujian, P.R.China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24962 Dated 24-09-2020
	Fee including differential fee	**Rs : 50,000** Dated 23-09-2020
	Brand Name +Dosage Form + Strength	Falvopak 80 Premix
	Composition	Each Kg contains: Bambermycin…80gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 201100B0/022161 issued by Animal Husbandry Bureau of Zhumadian City, Henan Province China Date of issuance: 31-03-2020 ➢ Original Legalized GMP Certificate No. (2019) GMP13004 issued by Fujian Province Department of Agriculture and Rural Affairs Date of issuance: 02-09-2020 Validity: 01-09-2024 ➢ Original Legalized Power of Attorney dated 31-03-2020 for the applied product
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Differential fee Rs. 50,000/- for registration of generic drug product.

		• Provide long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.
	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.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Differential fee Rs. 50,000/- for registration of generic drug product.** • **Long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.**	
877.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 30041 Dated 10-11-2020
	Fee including differential fee	Rs : 100,000 Dated 10-11-2020
	Brand Name +Dosage Form + Strength	Enroflox 10% Injection 100ml
	Composition	Each ml Contains: Enrofloxacin…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Enro-Pro 10 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113561)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate.

		• Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
878.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 30040 Dated 10-11-2020
	Fee including differential fee	Rs : 100,000 Dated 10-11-2020
	Brand Name +Dosage Form + Strength	Nitrox 34% Injection 100ml
	Composition	Each ml Contains: Nitroxynil…340mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Nitroxl Forte Injection (100ml) of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106699)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter	

	• **legalized valid original FSC.** • **legalized valid original GMP certificate** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
879.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 30038 Dated 10-11-2020
	Fee including differential fee	Rs : 100,000 Dated 10-11-2020
	Brand Name +Dosage Form + Strength	Tylo 20% Injection 100ml
	Composition	Each ml Contains: Tylosin…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Tomit-20 Injection (100ml) of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 099437)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Original GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Original distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	

	• **Submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
880.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 30039 Dated 10-11-2020
	Fee including differential fee	Rs : 100,000 Dated 10-11-2020
	Brand Name +Dosage Form + Strength	Amoxi 15% Injection 100ml
	Composition	Each ml Contains: Amoxicillin…150mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Vime-Amox 15% La Veterinary Liquid Injection (100ml) of M/s Al-Asar Enterprises, Multan. (Reg. No. 094478)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **(Scope of submitted GMP certificate** Validity: 26-01-2021 **does not cover penicillin injectable)** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission; Moreover,** Scope of submitted GMP certificate does not cover penicillin injectable Provide legalized valid original relevant GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following • **legalized original valid FSC** • **legalized original valid relevant GMP certificate**	

	• **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
881.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34454 Dated 28-12-2020
	Fee including differential fee	Rs : 100,000 Dated 23-12-2020
	Brand Name +Dosage Form + Strength	Ivermec 1% Injection 100ml
	Composition	Each ml Contains: Ivermectin…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Alfamec1% Solution for Injection (100ml) of M/s Chakwal Pharma International, Raiwind Road, Lahore (Reg. No.103795)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate** **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
882.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan

	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34456 Dated 28-12-2020
	Fee including differential fee	Rs : 100,000 Dated 23-12-2020
	Brand Name +Dosage Form + Strength	Ivermec 1% Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Vectin 1% Injection (50ml) of M/s Aamster Laboratories, Rawat, Islamabad. (Reg. No.103795) 109903
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate** **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
883.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).

	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34457 Dated 28-12-2020
	Fee including differential fee	Rs : 100,000 Dated 23-12-2020
	Brand Name +Dosage Form + Strength	Ivermclo 1%+10% Injection 100ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Clortin Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 113570)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate** **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
884.	Name and address of Applicant	M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazali Brothers Address: 19-SR-7 Azzainab Court, Campbell Street, Karachi Validity: 26-10-2023 Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China

	Name and address of marketing authorization holder	M/s Hebei Lihua Pharmaceutical Co. Ltd. No.1, Shuangjing East Road, Xinle City, Shijiazhuang City, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 34455 Dated 28-12-2020
	Fee including differential fee	Rs : 100,000 Dated 23-12-2020
	Brand Name +Dosage Form + Strength	Oxycline 20% Injection 50ml
	Composition	Each ml Contains: Oxytetracycline…200mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Levamycin-20% Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113400)
	Detail of certificates attached	➢ Copy of Legalized Free Sale Certificate No. 20200522 issued by Xinle Agriculture Forestry Animal Husbandry Bureau China Date of issuance: 18-05-2020 Validity: 2 Years ➢ Copy of GMP Certificate No. (2016) GMP03002 issued on 23-01-2017 **Validity: 26-01-2021** ➢ Copy of distribution agreement dated 08-04-2020 between PLH and the applicant for the applied product.**(original in Tylo injection 20% 100ml)**
	Remarks of the Evaluator [X]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The submitted copy of Free sale certificate (FSC) is **expired now, but valid upon submission,** Provide legalized valid original FSC. • The submitted copy of GMP certificate is **expired now, but valid upon submission,** Provide legalized valid original GMP certificate. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Approved. The firm shall submit following before issuance of registration letter • **legalized valid original FSC.** • **legalized valid original GMP certificate** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
885.	Name and address of Applicant	M/s Prix Pharmaceutica, 26 Abbot Road, Lahore, 54000, Pakistan
	Detail of Drug Sale License	Name: M/s Prix Pharmaceutica, Address: 26 Abbot Road, Lahore Validity: 12-06-2027. Status: License to sell drugs as Distributor (Form No.11).
	Name and address of manufacturer	M/s Eurovet Animal Health B.V., Handelsweg 25, PO Box 179, 5530 AD Bladel, The Netherlands

	Name and address of marketing authorization holder	M/s Eurovet Animal Health B.V., Handelsweg 25, PO Box 179, 5530 AD Bladel, The Netherlands
	Name of exporting country	The Netherlands
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 33720 Dated 18-12-2020
	Fee including differential fee	Rs : 50,000 Dated 18-12-2020
	Brand Name +Dosage Form + Strength	Revozyn RTU 400mg/ml Suspension for Injection
	Composition	Each ml Contains: Penethamate Hydroiodide…400mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Penicillin Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	**Netherlands approved**
	Me-too status	N/A
	Detail of certificates attached	➢ Photocopy of Legalized COPP No. 253161 dated 09-03-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands confirms the GMP status of the manufacturer as well as free sale status of the applied product in country of origin. ➢ Copy of distribution agreement/ letter of authorization **not provided**
	Remarks of the Evaluator [X]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The already submitted COPP is **photocopy,** Provide legalized valid original COPP. • Provide legalized valid original letter of Authorization (LOA) • Confirmation of dedicated penicillin injectable section. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for following • **legalized valid original COPP** • **legalized valid original letter of Authorization (LOA)** • **Confirmation of dedicated penicillin injectable section** • **Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
886.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd. Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Orient Animal Health Pvt Ltd, Address: Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi Validity: 22-10-2020. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Produlab Pharma BV. Forellenweg 16, NL-4941 SJ Raamsdonksveer, The Netherlands
	Name and address of marketing authorization holder	M/s EMDOKA bvba. John Lijsenstraat 16, B-2321 Hoogstraten Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A

	Diary No. & Date of R& I	Dy.No 23843 Dated 15-09-2020
	Fee including differential fee	Rs : 100,000 Dated 15-09-2020
	Brand Name +Dosage Form + Strength	Emdactilin 150 Solution For Injection
	Composition	Each ml Contains: 149.01mg of Spectinomycin HCl Pentahydrate Eq. To Spectinomycin…100mg 56.70mg Lincomycin HCl Monohydrate Eq. To Lincomycin…50mg
	Finished Product Specification	Eur. Ph
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	Belgium approved
	Me-too status	-
	Detail of certificates attached	➢ Original legalized Certificate of Pharmaceutical Product Certificate No. 000030 Issued on 23-05-2019, Certified by *Federal Agency for medicines and health products – famhp, Eurostation II, Victor Hortaplein 40/40, 1060 Brussels, Belgium*. The CoPP confirms free sale status of the product in exporting country ➢ Originally legalized copy of GMP certificate No. NL/V/17/0021 dated **05-10-2017** issued by the state Secretary of Economic Affairs, Head of the Veterinary Medicinal Products Unit, The Netherlands. ➢ Originally legalized sole agency certificate dated 26-09-2019 from PLH.
	Remarks of the Evaluator [X]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The already submitted GMP is **expired now but valid upon submission,** Provide legalized valid original GMP certificate. • Choice of one pack size. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following • **copy of valid DSL** • **original legalized valid GMP certificate** • **demanded pack size** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986**	
887.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd. Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Orient Animal Health Pvt Ltd, Address: Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi Validity: 22-10-2020. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Divasa-Farmavic, S.A. Ctra. Sant Hipolit, Km.71, Gurb-Vic, 08503 Barcelona, Spain
	Name and address of marketing authorization holder	M/s EMDOKA bvba. John Lijsenstraat 16, B-2321 Hoogstraten Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 23842 Dated 15-09-2020

	Fee including differential fee	Rs : 100,000 Dated 15-09-2020
	Brand Name +Dosage Form + Strength	Halagon 0.5mg/ml Oral Solution
	Composition	Each ml contains: Halofuginone as Lactate…0.5mg
	Finished Product Specification	Eur. Ph
	Pharmacological Group	Antiprotozoal
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	Not demanded
	International availability	Belgium approved
	Me-too status	-
	Detail of certificates attached	➢ Original legalized Certificate of Medicinal Product Certificate No. 02/19/136092 Issued on 20-09-2019, Certified by *European Medicine Agency*. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturer. ➢ Originally legalized GMP certificate No. ES/084HV/18 dated 13-07-2018 issued by Spanish agency of Medicines and Medical Devices, Spain Validity: 19-04-2020 **(expired even upon submission)** ➢ Originally legalized sole agency certificate dated 26-09-2019 from PLH attached in Emdactilin 150 Solution For Injection file
	Remarks of the Evaluator [X]	➢ 6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. ➢ The applied formulation is non-pharmacopoeial. **Shortcomings:** • The already submitted GMP is **expired even upon submission,** Provide • Choice of pack size. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following • **copy of valid DSL** • **original legalized valid GMP certificate** • **demanded pack size** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986**	
888.	Name and address of Applicant	M/s Lucky core Industries Limited, 5 West Wharf road Karachi (formerly M/s ICI Pakistan Limited, Karachi)
	Detail of Drug Sale License	Name: M/s Lucky core Industries Limited, Address: 5 West Wharf road Karachi Validity: 10-03-2026. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Anhui Apeloa Biotechnology Co., Ltd. Dongzhi Economic Development Zone, Anhui, P.R. China
	Name and address of marketing authorization holder	M/s Intervet International B.V Wim de korverstraat 35 5831 AN Boxmeer The Netherlands
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 32871 Dated 10-12-2020
	Fee including differential fee	Rs : 100,000 Dated 10-12-2020
	Brand Name +Dosage Form + Strength	Enradin F-40 premix
	Composition	Each Kg Contains:

		Enramycin…40gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	02 years
	Demanded Price	Decontrolled
	Pack size	2.5Kg, 5Kg, 20Kg
	International availability	**N/A**
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Originally legalized GMP certificate No. 2020 SY GMP ZZ 12001 dated 26-05-2020 issued by Department of Agriculture and Rural Affairs of Anhui Province China. Validity: 10-04-2025 ➢ Scanned copy of Authorization certificate dated 21-11-2019 from PLH to **ICI Pakistan Limited, Karachi** for the applied product
	Remarks of the Evaluator [X]	➢ The firm has submitted revised Form-5A alongwith fee Rs. 150,000/- dated 07-03-2023 vide slip No. 018299927485 for change of title. ➢ The applied formulation is non-pharmacopoeial. **Shortcomings:** • Status of Free sale in exporting country, since as per FSC the applied product is only licensed for export purpose. • Provide 6 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following • **Original legalized valid authorization letter/ sole agency certificate** • **Status of Free sale in country of origin.** • **6 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
889.	Name and address of Applicant	M/s Lucky core Industries Limited, 5 West Wharf road Karachi (formerly M/s ICI Pakistan Limited, Karachi)
	Detail of Drug Sale License	Name: M/s Lucky core Industries Limited, Address: 5 West Wharf road Karachi Validity: 10-03-2026. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Intervet International B.V. Wim De Korverstraat 35, 5831 An Boxmeer, Netherlands
	Name and address of marketing authorization holder	M/s Intervet International B.V. Wim De Korverstraat 35, 5831 An Boxmeer, Netherlands
	Name of exporting country	The Netherlands
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18534 Dated 28-07-2020
	Fee including differential fee	Rs : 100,000 Dated 28-07-2020

	Brand Name +Dosage Form + Strength	Cefa-Safe Intramammary Suspension
	Composition	One Intramemmary Syringe Of 9.3gm Contains: Cephapirin As Base (As Benzathine Salt)…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	02 years
	Demanded Price	Decontrolled
	Pack size	Box of 4 syringes, Box of 20 syringes
	International availability	**Could not be confirmed in the applied strength**
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Originally legalized CoPP No. 252128 dated 19-09-2019 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands confirms the GMP status of the manufacturer as well as free sale status of the applied product in country of origin. ➢ Authorization letter/ sole agency certificate **not provided**
	Remarks of the Evaluator [X]	➢ The firm has submitted revised Form-5A alongwith fee Rs. 150,000/- dated 07-03-2023 vide slip No. 95948708400 for change of title. ➢ Monograph of the applied formulation exists in USP. **Shortcomings:** • Provide 6 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of dedicated manufacturing facility • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following • **Original legalized valid authorization letter/ sole agency certificate** • **6 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Confirmation of dedicated manufacturing facility** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	

Agenda of Evaluator PEC-XI

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

890.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 06-10-2020 based on inspection conducted on 19-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy No. 2808 dated 28-01-2022
	Details of fee submitted	Rs. 30,000/- dated 29-11-2021 (Deposit silp#3175710812)
	The proposed proprietary name / brand name	Nubaquel XR 150mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release film coated tablet contains: Quetiapine Fumarate USP equivalent to Quetiapine……....150mg
	Pharmaceutical form of applied drug	Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Antipsychotics; Diazepines, oxazepines, thiazepines and oxepines.
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SEROQUEL XR (50mg, 150mg, 200mg, 300mg, 400mg) film coated extended-release tablets USFDA approved.
	For generic drugs (me-too status)	Qutyl XR 150mg Tablet by M/s CCL Pharmaceuticals, (Reg. No. 097647)
	Name and address of API manufacturer.	M/s ZCL Chemicals Ltd., Plot No. 3102/B, GIDC Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (QTP4200316, QTP4200416, QTP4200516)
	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 brand that is Qutyl XR tablets 150mg by performing quality tests (Description, Identification, Dissolution and Assay) CDP has been performed against the same brand that is Qutyl XR Tablet 150mg by M/s CCL Pharmaceuticals, in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and QC release media. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s ZCL Chemicals Ltd., Plot No. 3102/B, GIDC Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India		
API Lot No.	QTP-4207520		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	400DS01	400DS02	--
Batch Size	5000 tablets	5000 tablets	--
Manufacturing Date	03-2021	03-2021	--
Date of Initiation	13-03-2021	13-03-2021	--
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s ZCL Chemicals Ltd., 3102/B, GIDC Industrial Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India issued by Commissioner Food & Drug Control Administration Gujarat State India valid upto 06-07-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2220191 dated 23-10-2020 for import of 100Kg of Quetiapine Fumarate USP (Batch No# QTP4207520) from M/s ZCL Chemicals Ltd., India in name of M/s Nabiqasim Industries (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 03-12-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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	Certificate for HPLC software 21CFR compliance is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response

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. • Justification is required for not including test for fumaric acid content in drug substance specification by drug product manufacturer as recommended by drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance by drug product manufacturer is submitted. • As per USP monograph of Quetiapine drug substance, USP does not mention to perform fumaric acid content test. But as per drug substance manufacturer specifications fumaric acid content test is provided additionally, we have revised our API release specifications which include test for fumaric acid content for QC release. The firm has submitted revised drug substance specifications
3.2.P.2	• Justification is required since pharmaceutical equivalence and CDP have not been conducted against the innovator product. • Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as recommended by USP • Firm shall submit the image/picture/snapshot of 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 No# and expiry date of innovator/reference/comparator product in the section 3.2.P.2.2.1 (Formulation Development) of form 5F	• The firm submitted that Reference to CTD guidance document pharmaceutical equivalence and CDP studies can be perform against reference/ comparator sample. • The firm submitted that we have conducted uniformity of dosage unit test by mass variation as on today basis against reference sample and submitted the comparative results. • The firm has submitted Image picture/snapshot of reference pack against which pharmaceutical equivalence/comparative dissolution profile studies were performed.
3.2.P.7	• You have given specifications HDPE Jars while manufactured formulation in Alu-Alu packing, justify?	• The firm submitted that we acknowledge it was a mistake, our manufactured formulation is in Alu-Alu packaging. Specification for primary packaging is submitted.
3.2.P.8	• Submit audit trail reports on product testing	• Audit trail reports on product testing is submitted

Decision: Approved.

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

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Pharmaceutical equivalence and CDP studies against the innovator product.**

891.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 06-10-2020 based on inspection conducted on 19-09-2020.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy No. 399 dated 05-01-2022
	Details of fee submitted	Rs. 30,000/- dated 29-11-2021 (Deposit silp#248351610523)
	The proposed proprietary name / brand name	Nubaquel XR 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release film coated tablet contains: Quetiapine Fumarate USP equivalent to Quetiapine……....200mg
	Pharmaceutical form of applied drug	Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Antipsychotics; Diazepines, oxazepines, thiazepines and oxepines.
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SEROQUEL XR (50mg, 150mg, 200mg, 300mg, 400mg) film coated extended-release tablets USFDA approved.
	For generic drugs (me-too status)	Qutyl XR 200mg Tablet by M/s CCL Pharmaceuticals, (Reg. No. 097646)
	Name and address of API manufacturer.	M/s ZCL Chemicals Ltd., Plot No. 3102/B, GIDC Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (QTP4200316, QTP4200416, QTP4200516)
	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 brand that is Qutyl XR tablets 200mg by performing quality tests (Description, Identification, Dissolution and Assay) CDP has been performed against the same brand that is Qutyl XR Tablet 200mg by M/s CCL Pharmaceuticals, in Acid media (pH 1.2), acetate buffer (pH 4.5), Phosphate Buffer (pH 6.8) and QC release media. The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, range, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s ZCL Chemicals Ltd., Plot No. 3102/B, GIDC Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India		
API Lot No.	QTP-4207520		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	399DS01	399DS02	--
Batch Size	5000 tablets	5000 tablets	--
Manufacturing Date	03-2021	03-2021	--
Date of Initiation	13-03-2021	13-03-2021	--
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s ZCL Chemicals Ltd., 3102/B, GIDC Industrial Estate Ankleshwar-393002 Dist.-Bharuch, Gujarat, India issued by Commissioner Food & Drug Control Administration Gujarat State India valid upto 06-07-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2220191 dated 23-10-2020 for import of 100Kg of Quetiapine Fumarate USP (Batch No# QTP4207520) from M/s ZCL Chemicals Ltd., India in name of M/s Nabiqasim Industries (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 03-12-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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	Certificate for HPLC software 21CFR compliance is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
3.2.S.4	• Justification is required for not including test for fumaric acid content in	• As per USP monograph of Quetiapine drug substance, USP does not mention to perform

	drug substance specification by drug product manufacturer as recommended by drug substance manufacturer	fumaric acid content test. But as per drug substance manufacturer specifications fumaric acid content test is provided additionally, we have revised our API release specifications which include test for fumaric acid content for QC release. The firm has submitted revised drug substance specifications
3.2.P.2	• Justification is required since pharmaceutical equivalence and CDP have not been conducted against the innovator product. • Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as recommended by USP • Firm shall submit the image/picture/snapshot of 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 No# and expiry date of innovator/reference/comparator product in the section 3.2.P.2.2.1 (Formulation Development) of form 5F	• The firm submitted that Reference to CTD guidance document pharmaceutical equivalence and CDP studies can be perform against reference/ comparator sample. • The firm submitted that we have conducted uniformity of dosage unit test by mass variation as on today basis against reference sample and submitted the comparative results. • The firm has submitted Image picture/snapshot of reference pack against which pharmaceutical equivalence/comparative dissolution profile studies were performed.
3.2.P.5	• The copies of complete analysis of at least two batches shall be provided.	The firm has submitted copies of Certificate analysis of two batches.
3.2.P.8	• Submit audit trail reports on product testing	Audit trail reports on product testing is submitted

Decision: Approved.

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

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Pharmaceutical equivalence and CDP studies against the innovator product**

892.	Name, address of Applicant / Marketing Authorization Holder	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145-149, North Western Industrial Zone, Port Qasim, Karachi.
	Name, address of Manufacturing site.	M/s Hiranis Pharmaceuticals (Pvt.) Ltd., Plot No. E-145-149, North Western Industrial Zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 12-11-2021 based on inspection conducted on 05-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-33/2009-Lic dated 07-02-2014 which specifies Tablet (General) section
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1198 dated 13/01/2022

	Details of fee submitted	PKR 75,000/- dated 13/12/2021 (Deposit slip#6303718587)
	The proposed proprietary name / brand name	**Tedizol 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tedizolid Phosphate……200mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Oxazolidinone Antibiotics
	Reference to Finished product specifications	Not in pharmacopeia
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sivextro 200mg film coated Tablet USFDA Approved. Sivextro 200mg film-coated tablets MHRA Approved Sivextro 200mg film-coated tablets Health Canada Approved
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	M/s Yibin Hongguang Pharmaceutical Co. Ltd., Luolong County Nanxi District, Yibin City, Sichuan Province 644100, 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of 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: (MS102302-180101, MS102302-180102, MS102302-180103)
	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 innovator brand Sivextro 200mg Tablet by M/s PatheonInc, Canada by performing quality tests (Identification, disintegration time, Assay, Dissolution, average weight). CDP has been performed against the same brand that is Sivextro 200mg Tablet by M/s PatheonInc, Canada in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). It was found that both reference & test products were not soluble in 0.1N HCl buffer till 180 minutes therefore similarity and difference factors f2 were calculated which is greater than 50. The

		dissolution of both the innovator product and test product is more than 85% in the acetate buffer and phosphate buffer so values of f2 is not calculated.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, system suitability, robustness, LOD and LOQ.

STABILITY STUDY DATA

Manufacturer of API	M/s Yibin Hongguang Pharmaceutical Co. Ltd., Luolong County Nanxi District, Yibin City, Sichuan Province 644100, China		
API Lot No.	MS102302-201101		
Description of Pack (Container closure system)	Alu-PVDC blister packed in unit carton (1×6's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF-040321A	TF-040321B	TF-040321C
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	11-03-2021	11-03-2021	11-03-2021
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)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 294th meeting dated 09th April, 2020 decided to approve registration of Etoxib 90 & 120mg tablet. Inspection date: 29th October, 2019 (Morning) The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. • Audit Trail on the testing reports are available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate in name of M/s Yibin Hongguang Pharmaceutical Co. Ltd., Luolong County Nanxi District, Yibin City, Sichuan Province China issued by ***Yibin Association for Pharmaceutical Industry*** valid upto 16-03-2025. Firm has submitted Copy of DML (No. 20170447) in name of M/s Yibin Hongguang Pharmaceutical Co. Ltd., Luolong County Nanxi District, Yibin City, Sichuan Province China valid upto 29-12-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. MCI20210108-002 dated 08-01-2021 for import of 01kg of Tedizolid Phosphate (Batch No# MS102302-201101) in name of M/s Hiranis Pharmaceuticals (Pvt) Ltd attested by AD (I&E) DRAP Karachi dated 02-02-2021. Firm has also submitted copy of form 6 dated 02-02-2021 for import of 01kg of Tedizolid Phosphate in name of M/s Hiranis Pharmaceuticals (Pvt) Ltd attested by AD (I&E) DRAP Karachi dated 02-02-2021.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

INDICATIONS AND USAGE

Acute Bacterial Skin and Skin Structure Infections

SIVEXTRO® is an oxazolidinone-class antibacterial indicated in adult and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.

Section	Observations	Response
3.2.S.4	• Justification is required for not including test for residue on ignition, bacterial endotoxins and microbial limits in drug substance specifications by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document.	The firm submitted that our proposed product is film-coated tablet, therefore test for Bacterial endotoxin and microbial limit is not the part of Drug substance specifications. Test for residue on ignition is not included in routine testing of Drug substance manufacturer but it was addressed as in-organic impurities during product development with less than 0.2% limit and not included in routine testing based on process validation and submitted documents from drug substance manufacturer as evidence. The firm further stated that drug product manufacturer did not include above tests based on drug substance manufacturer specifications and intended used of drug substance.
3.2.P.2	• Justify the difference in time point in CDP studies in three physiological medias. (180 min in Acid media, 15 min acetate buffer and 30 min phosphate buffer)	The firm submitted that we have conducted CDP in three recommended dissolution medium and difference in time point is due to API solubility behavior at different pH. In acetate buffer pH 4.5 and phosphate buffer pH 6.8, drug release found more than 85% in 15 minutes, while in 0.1N HCl, we observed a plateau of drug release around 8% until 180 minutes. In the case where 85% dissolution cannot be reached owing to poor solubility of the API or the release mechanism of the dosage form, the dissolution should be conducted until an asymptote (plateau) has been reached.
3.2.P.5	• Justification is required for selecting dissolution specification NLT Q in 30 minutes instead of NLT Q in 20 minutes as recommended by innovator product review document • Justification is required for not including the test for water content in finished product specification as recommended by innovator product review document	• The firm submitted that we have selected dissolution time point 30minutes considering BCS class II of tedizolid phosphate and sampling time recommended in FDA dissolution database. In case when drug product dissolution test in not available in any official pharmacopoeia, but all or some details of dissolution parameters are publicly available at FDA dissolution database, FDA CMC review, PAR of reference regulatory authority, review report of PMDA Japan. It is recommended to follow the dissolution

		parameters if provided in FDA dissolution methods database. ***However, the innovator product review document recommends dissolution specification NLT Q in 20 minutes instead of NLT Q in 30 minutes*** • The firm submitted that since Tedizolid phosphate is non-hygroscopic anhydrous solid, we have control the water/moisture content during manufacturing of drug product with specification between 1-2% and same was tested during in-process control.
	3.2.P.8 • The submitted chromatograms shows that different column oven temperature and flow rate (45ºC and 0.6ml/min) was used in analysis than that mentioned in analytical procedure (30ºC and 0.8ml/min), justify	• The firm submitted that the submitted chromatograms & related analysis is done in-accordance to parameters defined in analytical method validation i.e. flow rate 0.6ml/min & column temperature 45°C. • The old version of analytical method submitted in registration dossier by mistake. The firm submitted that we are enclosing revised method in accordance to AMV studies and submitted revised complete analytical method.

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.**
- **Manufacturer will adopt dissolution specifications of "NLT Q in 20minutes", for commercial batches.**

Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

893.	Name, address of Applicant / Marketing Authorization Holder	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim Karachi
	Name, address of Manufacturing site.	M/s PharmEvo (Pvt.) Ltd., Plot No. A-29, North Western Industrial Zone, Port Qasim 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 17th September, 2020 based on inspection conducted on 16th September 2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-1/98-Lic (Vol-II) dated 21-02-2018 which specifies Tablet (General) section (Revised)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 155 dated 03/01/2022
	Details of fee submitted	PKR 30,000/-: dated 14/12/2021 (Deposit slip#489570495)
	The proposed proprietary name / brand name	**Oxivort 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vortioxetine as Hydrobromide …… 15mg
	Pharmaceutical form of applied drug	Film coated tablet

	Pharmacotherapeutic Group of (API)	Antidepressants
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	7's, 10's, 14's, 20's, 28's, 30's, 56's, 84's, 100's, 122's
	The status in reference regulatory authorities	TRINTELLIX 15mg film coated tablet USFDA Approved. *****Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons***** Brintellix 15 mg film-coated tablets MHRA Approved
	For generic drugs (me-too status)	Vorneu Tablet 15mg by M/s Hilton Pharma (Reg. No#107778)
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceutical Co., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huainan, Jiangsu China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 36 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (X231303161, X231303231, X231303301)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Vorneu 15mg Tablet by M/s Hilton Pharma by performing quality tests (Identification, Assay, Dissolution, content uniformity, disintegration time). CDP has been performed against the same brand that is Vorneu 15mg Tablet by M/s Hilton Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The release of both the comparator product and test product is more than 85% in all the three media so values of f2 is not calculated.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, Intermediate precision, repeatability, specificity, LOD and LOQ.
STABILITY STUDY DATA		

Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huainan, Jiangsu China		
API Lot No.	3804-201807001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19PD-2769-02-T	19PD-2770-03-T	19PD-2771-04-T
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	14-06-2019	14-06-2019	14-06-2019
Date of Initiation	26-07-2019	26-07-2019	26-07-2019
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)	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 293rd meeting dated 6th-8th January, 2020 decided to approve registration of Empagin XR Tablets 5/1000mg, Empagin XR Tablets 10/1000mg, Empagin XR Tablets 12.5/1000mg, Empagin XR Tablets 25/1000mg. Inspection date: 05th December, 2019 The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. • Audit Trail on the testing reports are available. • The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All chambers are properly qualified. All chambers are provided with continuous power supply and data loggers for continuous monitoring.
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 in the name of M/s Jiangsu Yongan Pharmaceutical Co., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China ***issued by Huaian Pharmaceutical Industry Association No. 168, West Chaoyang Road, Qingpu Industrial Park, Huaian, Jiangsu*** valid upto 14-01-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZY18083101G/W dated 31-08-2018 for import of 900g of Vortioxetine Hydrobromide (Batch No# 3804-201807001) in name of M/s PharmEvo (Pvt) Ltd attested by AD (I&E) DRAP Karachi dated 24-09-2018. Firm has also submitted copy of form 6 dated 24-09-2018 for import of 900g of Vortioxetine Hydrobromide in name of M/s PharmEvo (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 24-09-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Fir 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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. TRINTELLIX is not approved for use in pediatric patients.

Section	Observations	Response
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for issued by relevant regulatory authority of country of origin is required	• The firm has submitted DML # (Su 20160324) of M/s Jiangsu Yongan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China valid upto December 06, 2025.
3.2.S.4	• Justification is required for not including test for polymorph confirmation (β-polymorph), particle size distribution and microbial contamination in drug substance specification by drug substance manufacturer as recommended by innovator product review document although results for polymorph confirmation and particle size distribution submitted in batch analysis • 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.	• The firm has submitted revised drug substance specifications containing tests for polymorph confirmation and particle size distribution by drug substance manufacturer • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance by drug product manufacturer is submitted • Analytical Method Verification studies including selectivity, linearity, repeatability (method precision), accuracy, system suitability and robustness performed by the Drug Product manufacturer for drug substance(s) is submitted.
3.2.P.2	• Justify why Pharmaceutical equivalence and CDP of the applied product is not performed against the innovator product • Firm shall submit the image/picture/snapshot of 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 No# and expiry date of innovator/reference/comparator product in the section 3.2.P.2.2.1 (Formulation Development) of form 5F	• The firm submitted that as per the guidance document for submission of applications on Form 5-F (CTD) for registration of pharmaceutical drug products for human use, pharmaceutical equivalence and CDP of the applied drug shall be established with the innovator, reference, or comparator product, since the innovator product i.e. Trintellix Tablet was not readily available in the market therefore comparator product was used to established Pharmaceutical Equivalence Studies and CDP. • Firm has submitted the image/picture/snapshot of innovator/reference/comparator pack against which pharmaceutical equivalence/comparative dissolution profile studies have been performed.
3.2.P.5	• Justification is required for dissolution specifications NLT 80% (Q); (Q+5=85%) in 30min instead of NLT Q in 20min as recommended by innovator product review document • Justification is required since the limit of assay test in batch analysis of Batch No# 19PD-2769-02-T is out of specifications 140.33% (Limits 90-110%)	• The firm submitted that the Center for Drug Evaluation and Research recommends dissolution specifications of NLT 80% (Q); (Q+5=85%) in 30 minutes based on the chemistry review. • The firm submitted that we would like to inform your kind authority that there is a typographical error in the batch analysis; the correct result of the assay is 104.33%

		(limit 90–110%), which is within a limit. A COA is attached for confirming a result.

Decision: Approved with innovator's specifications.

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

Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

BOX WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. TRINTELLIX is not approved for use in pediatric patients.

894.	Name, address of Applicant / Marketing Authorization Holder	M/s Dyson Research Laboratories Pvt. Ltd., 28-km, Ferozepur Road, Lahore.
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt. Ltd., 28-km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-7/2003-Lic (Vol-IV) dated 08-06-2021 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1892 dated 20/01/2022
	Details of fee submitted	PKR 50,000/-: dated 09/12/2020
	The proposed proprietary name / brand name	**Dyzan 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as fumarate……..10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Proton Competitive acid blocker (P-CAB)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 10mg tablet by M/s Takeda Pharmaceutical Company Limited, PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti Tablet 10mg by M/s The Searle Company Limited, (Reg. No. 108835)
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and

		controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of 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 of Drug Substance (Conditions & duration of Stability studies)	Not submitted
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator brand that is Takecab 10mg Tablet by M/s Takeda Pharmaceutical Company Limited, Japan, by performing quality tests (Identification, Assay, Dissolution, average weight). CDP has been performed against the same brand that is Takecab 10mg Tablet, by M/s Takeda Pharmaceutical Company Limited, Japan, in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD & LOQ, robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China		
API Lot No.	20190801BD		
Description of Pack (Container closure system)	PVC-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	800 tab	800 tab	800 tab
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	28-12-2019	28-12-2019	28-12-2019
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)	N/A

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Jiangxi Province, P.R. China issued by ***Jiangxi API Engineering Technology Research Center*** valid upto 11-03-2025. Firm has submitted Copy of DML (No. 20160125) in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China valid upto 26-11-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. JXSG190952 dated 16-10-2019 for import of 0.11kg of Vonoprazan Fumarate (Batch No# 20190801BD) in name of M/s Dyson Research Laboratories. However, the invoice is not attested by AD (I&E) DRAP filed office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Clarification is required as the fee is submitted almost 1 year and 1 month before the R&I date of submitted application. Furthermore, Fee challan is not endorsed by AD budget and accounts division DRAP	• The firm has submitted new fee of Rs. 30,000/- as the fee for registration of generic drug, on deposit slip no. 110777790, dated 03-03-2023.
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	Firm has submitted cGMP certificate issued on 16-01-2023 based on inspection conducted on 03-11-2021.
3.2.S.2	• You have submitted details of manufacturer of drug substance as M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Flouride industrial Park, Fumeng County, Fuxin City, Liaoning Province China instead of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China as provided in section 1.6.5, clarify	• The firm submitted that the manufacturer of Drug substance is M/s. Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China. And all the related documents including GMP, Invoice, etc. are of the above mentioned company. M/s. Fuxin Long Rui Pharmaceutical Co. Ltd., in section 3.2.S.2 is written by mistake and is a typographic error.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Copies of Drug substance specifications and analytical procedures used for routine testing of the Drug Substance by Drug substance manufacturer is submitted.
3.2.S.8	• Submit stability study data of drug substance from drug substance manufacturer till claimed shelf life	• Stability data of drug substance till claimed shelf life is submitted: Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20190801BD, 20190802BD, 20190803BD).
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	• ***Compatibility study of Drug substance along with excipients is not submitted***

	Applied product	**TAKECAB OD Tablets 10mg**
	Vonoprazan Fumarate	Vonoprazan Fumarate
	Mannitol, Microcrystalline cellulose (Avicel Ph 102), hydroxypropyl cellulose, Cross carmeloose sodium, magnesium stearate, new coat white, tartarizne lake color, purified water	D-mannitol, crystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, iron sesquioxide
3.2.P.5	• Justification to be provided for the selection of dissolution parameters including dissolution media buffer (6.8):water (1:1), volume of dissolution medium, rpm and type of USP apparatus	The dissolution parameters are established as per ICH Q6A guidelines following the guidance of USP chapter <1092>. • The dissolution profile of dosage form is rapid i.e., Dissolution >80% in 15 minutes at pH 1.2, 4.5 and 6.8. • Also the dose solubility ratio remains very high throughout the physiological buffer range i.e., 5.2mg/ml in pH 6.8 buffer, 18.3mg/ml in pH 1.2 buffer and 10.4 mg/ml in pH 4.5 buffer. • Therefore, we have selected dissolution medium having pH 6.8. Since the water ratio is in equal proportion i.e., buffer (6.8) : water (1:1), it has no effect on the pH and it remain same as 6.8. • The selected rpm is 50 with 900ml medium and 15 minutes sampling time with apparatus II, as per guidelines of USP chapter
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP.	Firm has submitted copy of invoice No. JXSG190952 dated 16-10-2019 for import of 0.11Kg of Vonoprazan Fumarate (Batch No# 20190801BD) in name of M/s Dyson Research Laboratories Lahore., attested by AD (I&E) DRAP Lahore dated 31-10-2019.

Decision: Approved with innovator's specifications.

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

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Compatibility studies of the Drug Substance with excipients**

895.	Name, address of Applicant / Marketing Authorization Holder	M/s Dyson Research Laboratories Pvt. Ltd., 28-km, Ferozepur Road, Lahore.
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt. Ltd., 28-km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-7/2003-Lic (Vol-IV) dated 08-06-2021 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1893 dated 20/01/2022
	Details of fee submitted	PKR 50,000/-: dated 09/12/2020
	The proposed proprietary name / brand name	Dyzan 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vonoprazan as fumarate……..20mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Proton Competitive acid blocker (P-CAB)
	Reference to Finished product specifications	Innovator
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab 20mg tablet by M/s Takeda Pharmaceutical Company Limited, PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti Tablet 20mg by M/s The Searle Company Limited, (Reg. No. 108836)
	Name and address of API manufacturer.	M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of 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 of Drug Substance (Conditions & duration of Stability studies)	Not submitted
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator brand that is Takecab 20mg Tablet by M/s Takeda Pharmaceutical Company Limited, Japan,

		by performing quality tests (Identification, Assay, Dissolution, average weight). CDP has been performed against the same brand that is Takecab 20mg Tablet, by M/s Takeda Pharmaceutical Company Limited, Japan, in Acid media (0.1N HCl), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD & LOQ, robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China		
API Lot No.	20190801BD		
Description of Pack (Container closure system)	PVC-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	800 tab	800 tab	800 tab
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	28-12-2019	28-12-2019	28-12-2019
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Jiangxi Province, P.R. China issued by ***Jiangxi API Engineering Technology Research Center*** valid upto 11-03-2025. Firm has submitted Copy of DML (No. 20160125) in name of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China valid upto 26-11-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. JXSG190952 dated 16-10-2019 for import of 0.11kg of Vonoprazan Fumarate (Batch No# 20190801BD) in name of M/s Dyson Research Laboratories. However, the invoice is not attested by AD (I&E) DRAP filed office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Clarification is required as the fee is submitted almost 1 year and 1 month before the R&I date of submitted application. Furthermore, Fee challan not endorsed by AD budget and accounts division DRAP	• The firm has submitted new fee of Rs. 30,000/- as the fee for registration of generic drug, on deposit slip no. 1112666231, dated 03-03-2023.
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	Firm has submitted cGMP certificate issued on 16-01-2023 based on inspection conducted on 03-11-2021.
3.2.S.2	• You have submitted details of manufacturer of drug substance as M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Flouride industrial Park, Fumeng County, Fuxin City, Liaoning Province China instead of M/s Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China as provided in section 1.6.5, clarify	• The firm submitted that the manufacturer of Drug substance is M/s. Jiangxi Synergy Pharmaceutical Co. Ltd., Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Province, P.R. China. And all the related documents including GMP, Invoice, etc. are of the above mentioned company. M/s. Fuxin Long Rui Pharmaceutical Co. Ltd., in section 3.2.S.2 is written by mistake and is a typographic error.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Copies of Drug substance specifications and analytical procedures used for routine testing of the Drug Substance by Drug substance manufacturer is submitted.
3.2.S.8	• Submit stability study data of drug substance from drug substance manufacturer till claimed shelf life	• Stability data of drug substance till claimed shelf life is submitted: Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20190801BD, 20190802BD, 20190803BD).
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	• ***Compatibility study of Drug substance with excipients is not submitted***
3.2.P.5	• Justification to be provided for the selection of dissolution parameters including dissolution media buffer (6.8):water (1:1), volume of dissolution medium, rpm and type of USP apparatus	The dissolution parameters are established as per ICH Q6A guidelines following the guidance of USP chapter <1092>. • The dissolution profile of dosage form is rapid i.e., Dissolution >80% in 15 minutes at pH 1.2, 4.5 and 6.8. • Also the dose solubility ratio remains very high throughout the physiological buffer range i.e., 5.2mg/ml in pH 6.8 buffer, 18.3mg/ml in pH 1.2 buffer and 10.4 mg/ml in pH 4.5 buffer.

Applied product	**TAKECAB Tablets 20mg**
Vonoprazan Fumarate	Vonoprazan Fumarate
Mannitol, Microcrystalline cellulose (Avicel Ph 102), hydroxypropyl cellulose, Cross carmeloose sodium, magnesium stearate, new coat white, tartarizne lake color, purified water	D-mannitol, crystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide, iron sesquioxide

		• Therefore, we have selected dissolution medium having pH 6.8. Since the water ratio is in equal proportion i.e., buffer (6.8) : water (1:1), it has no effect on the pH and it remain same as 6.8. • The selected rpm is 50 with 900ml medium and 15 minutes sampling time with apparatus II, as per guidelines of USP chapter
3.2.P.8	• You have mentioned packing of applied product in ALU-PVC blister packing in section 3.2.P.7 while Alu-Alu blister packing in stability summary sheet of this section, clarify • Submit documents for the procurement of API with approval from DRAP.	• The firm submitted that we have followed the packaging of innovator brand that is Takecab 20mg tablet with Alu-PVC blister pack. Alu-Alu blister in stability summary sheet is a typographic error, we have revised the sheets and submitted revised summary sheets. The firm has also submitted specifications of container closure system in section 3.2.P.7. • Firm has submitted copy of invoice No. JXSG190952 dated 16-10-2019 for import of 0.11Kg of Vonoprazan Fumarate (Batch No# 20190801BD) in name of M/s Dyson Research Laboratories Lahore., attested by AD (I&E) DRAP Lahore dated 31-10-2019.

Decision: Approved with innovator's specifications.

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

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Compatibility studies of the Drug Substance with excipients**

896.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt.) Ltd., 44-45B Korangi Creek Road Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., 44-45B Korangi Creek Road Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-12/93-Lic (Vol-V) dated 20-09-2021 which specifies Liquid Injection (Ampoule, Vial, Infusion) (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. 1013 dated 11-01-2022
	Details of fee submitted	PKR 75,000/-: dated: 23-12-2021 (Deposit sip#8155830888)
	The proposed proprietary name / brand name	**Genfer Injection 100mg/2ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ferric hydroxide polymaltose complex equivalent to Iron(III)……100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Use to treat Iron deficiency
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	5's x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ferrosig Injection 100mg/2ml by M/s Sigma Company Limited., TGA Approved
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 36 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 002 FP 01, FPJ 003 FP 01, FPJ 004 FP 01)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Hemafer 100mg/2ml Injection by M/s UNI-PHARMAKLEON LAORATORIES S.A by performing quality tests (Identification, pH, Assay)
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, Accuracy, Precision-Repeatability, Intermediate Precision, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy
API Lot No.	FPJ014FV20
Description of Pack	Amber glass Type I ampoule

(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.	21SB(A)-098-01	21SB(A)-099-02	21SB(A)-100-03
Batch Size	500ampoules	500ampoules	500ampoules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	15-07-2021	15-07-2021	15-07-2021
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate in name of Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy issued by Italian Medicines Agency valid upto three years from the date of inspection (date of inspection 28/06/2019)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for three months is submitted

Remarks of Evaluator [XI]:

THERAPEUTIC INDICATIONS

FERROSIG is indicated for the treatment of iron deficiency anaemia in the following circumstances:

- When oral therapy is contraindicated.
- When enteric absorption of iron is defective.
- When patient non-compliance or persistent gastrointestinal intolerance makes oral therapy impractical.

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of cGMP certificate issued on 07-10-2021 based on inspection conducted on 15-06-2021.
1.5.5	• Submit correct Pharmacological class of the drug substance with proper reference	• Parenteral iron preparations. Anti-anaemic
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm submitted clarification from AIFA Italy stating that due to restrictions caused by covid-19, the period of validity of the GMP certificate is automatically extended until the end of 2023. Onsite inspections will resume as soon as there is a consensus that the period of public health crisis has passed
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Not submitted

3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	According to Biofer MOA no working standard are required for release analysis of the API Ferric Hydroxide Polymaltose Complex so, we cannot provide any CoA.
3.2.S.7	• Results of Assay test for iron is not submitted in stability study of drug substance, clarify	Firm submitted revised real time stability study data of drug substance wherein Assay test for iron and polymaltose has been performed. However, time point of stability study as per ICH guideline is not submitted. Furthermore accelerated stability study data is not submitted.
3.2.P.1	• Justification is required for not using hydrochloric acid or sodium hydroxide for pH adjustment in formulation	• In development of Genfer Injection 100mg/2ml, the active substance (Ferric Hydroxide Polymaltose Complex Inj.Grade) is dissolved in water for injection and mix until homogenization of solution will be formed. Then Check the pH of the solution. pH limit = 5.2 – 6.50. • The pH of the solution observed in the range as described above therefore no need to the addition of HCl or NaOH for pH adjustment in the formulation. • The product kept on stability and no changes observed in pH of the formulation and any other physical and chemical parameters. • Stability studies also demonstrated that the formulation is stable without the addition of pH adjusting agents.
3.2.P.2	• Submit details of country of origin of reference product against which pharmaceutical equivalence studies have been performed. • Justification is required for not performing test for bacterial endotoxin and particulate matter in pharmaceutical equivalence as submitted in finished product specifications	• The firm submitted details of country of origin: UNI-PHARMA KLEON TSETIS Pharmaceutical Laboratory S.A 14Km National Road 1, GR-145 64K, Kifissia GREECE • The firm has submitted revised pharmaceutical equivalence report wherein results of test for bacterial endotoxin and particulate matter has been submitted
3.2.P.5.2	• You have applied for innovator specifications in module 1 section 1.5.6 while in-house specification in this section, justify?	The firm submitted that this is typographic error and submitted revise specification stating innovator specifications
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	We have conducted assay of Iron by complexometric titration, in this method working standard is not required.
3.2.P.8	• You have written liraglutide on initial page of summary sheet while applied product is ferric hydroxide polymaltose complex, clarify? • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 6th months is required • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit 6th month stability data of applied product	• The firm submitted that this is typographic error and submitted corrected summary reports. • Audit trial is not applicable as product testing is carried out via titration method • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted • Firm has submitted copy of invoice for import of 01Kg of Ferric Hydroxide Polymaltose Complex (Batch No# FPJ014FV20) in name of M/s Genix Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 26-04-2021.

	• 6th month stability data of applied product is submitted
Decision: Deferred for submission of following: • **Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.** • **Stability study data of drug substance as per zone IV-A conditions till claimed shelf life.** • **Pharmaceutical equivalence of applied product against innovator product** • **Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

Case No. 02; Routine Registration application of Human drugs on Form 5F (Local) whose Replies are not received

897.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Wilshire Laboratories (Pvt.) Ltd., 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)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 05-09-2019 based on inspection conducted on 08-08-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-65/84-Lic (Vol-IV) dated 22-04-2021 which specifies Liquid Injectable (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	***Form-5 Dy.No 4507 dated 25-04-2019*** Applied on Form-5F Dy No. 400 dated 05-01-2022
	Details of fee submitted	***Rs. 20,000/- dated 24-04-2019*** ***Previous fee to be considered***
	The proposed proprietary name / brand name	Ketyre Injection 15mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule Contains: Ketorolac Tromethamine……15mg
	Pharmaceutical form of applied drug	Liquid Injectable solution
	Pharmacotherapeutic Group of (API)	Analgesic / anti-inflammatory
	Reference to Finished product specifications	USP
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Ketorolac Tromethamine 15mg/ml Injection by M/s Fresenius Kabi USA, USFDA Approved.
	For generic drugs (me-too status)	Not available in applied strength
	Name and address of API manufacturer.	M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications,

		analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 18 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: (CKTT/18001, CKTT/18002, CKTT/18003)
	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 product that is Toradol 15mg/1ml Injection by M/s Roche by performing quality tests (physical appearance, Identification, Assay, pH, sterility, bacterial endotoxin).
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, solution stability, linearity, range, Intermediate precision, repeatability, accuracy, robustness, LOD and LOQ.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India.		
API Lot No.	KTT/1002501		
Description of Pack (Container closure system)	1ml ampoule packed in foil in bleach board unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000 injection	1000 injection	1000 injection
Manufacturing Date	20-08-2020	25-08-2020	27-08-2020
Date of Initiation	16-08-2020	16-08-2020	16-08-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not submitted

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 0057/U2/E/19-20 dated 17-02-2020 for import of 0.8725Kg of Ketorolac Tromethamine (Batch No# KTT/1002501) from M*/s Vasudha Pharma Chem Limited, Unit-I Plot No. 37/A, 38, 39 A&B, Phase-I IDA Jeedimetla Hyderabad-500055 Telangana India* in name of M/s Wilshire Laboratories (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 28-02-2020. ***Address of* M*/s Vasudha Pharma Chem Limited is different from that given in section 3.2.S.2***
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	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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.2	• The firm submitted photocopy of receipt of fee ***Rs. 20,000/-*** submitted ***dated 24-04-2019*** • Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or Submit differential fee as the applied product is a new formulation (strength)
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.5.5	• Submit correct Pharmacological class of the drug substance with proper reference
1.6.5	• Submit Name and address of drug substance manufacturer • Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
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) ketorolac trimethylamine is submitted. • Clarification is required as drug substance manufacturer has mentioned the name of drug substance in batch analysis as ketorolac tromethamine while you have mentioned ketorolac triethylamine • Drug product manufacturer has not performed the Tromethamine Test for drug substance in batch analysis as recommended by USP • COA of drug substance from drug substance manufacturer is submitted from *M/s Vasudha Pharma Chem Limited, unit-I Plot No. 39, A&B, Phase-I IDA Jeedimetla Hyderabad-500055 Telangana India* while drug substance manufacturer details provided in section 3.2.S.2 is *M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India, clarify*
3.2.P.2	• Justify the role of Ethyl alcohol as preservative in the applied formulation. • Firm shall submit the image/picture/snapshot of 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 No# and expiry date of innovator/reference/comparator product in the section 3.2.P.2.2.1 (Formulation Development) of form 5F
3.2.P.3.3	• Justify the performance of terminal sterilization by autoclave since reference product review document does not recommend terminal sterilization.
3.2.P.5	• Justification is required for preparing different concentration of stock solution and standard solution in assay analytical method from that recommended by USP.

	• Justification is required for using internal standard in assay method which is not recommended by USP • Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not included in specification • The manufacturing date of trial batches mentioned in batch analysis (13-08-2020, 20-08-2020, 25-08-2020) is different from that mentioned in submitted BMR (20-08-2020, 25-08-2020, 27-08-2020), clarify • Clarification is required as you have mentioned the generic name of drug substance in batch analysis as ketorolac triethylamine instead of ketorolac tromethamine.
3.2.P.7	• Applied product packed in ampoule while reference product packed in vial
3.2.P.8	• Justification shall be submitted as the date of initiation of stability study is before the manufacturing date of trial batches • The peak labelled in submitted chromatograms is vortioxetine while applied product is ketorolac tromethamine, clarification is required • As per submitted invoice drug substance is imported from M*/s Vasudha Pharma Chem Limited, Unit-I Plot No. 37/A, 38, 39 A&B, Phase-I IDA Jeedimetla Hyderabad-500055 Telangana India* while drug substance manufacturer details provided in section 3.2.S.2 is *M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India, clarify*

Decision: Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting fir reply.

898.	Name, address of Applicant / Marketing Authorization Holder	M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Wilshire Laboratories (Pvt.) Ltd., 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)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 05-09-2019 based on inspection conducted on 08-08-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-65/84-Lic (Vol-IV) dated 22-04-2021 which specifies Liquid Injectable (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	***Form-5 Dy.No 4509 dated 25-04-2019*** Applied on Form-5F Dy No. 1196 dated 13-01-2022
	Details of fee submitted	***Rs. 20,000/- dated 24-04-2019*** ***Previous fee to be considered***
	The proposed proprietary name / brand name	Ketyre Injection 60mg/2ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule Contains: Ketorolac Tromethamine……60mg
	Pharmaceutical form of applied drug	Liquid Injectable solution
	Pharmacotherapeutic Group of (API)	Analgesic / anti-inflammatory
	Reference to Finished product specifications	USP
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Ketorolac Tromethamine 60mg/2ml Injection by M/s Amphastar Pharm USFDA Approved.

	For generic drugs (me-too status)	Not available in applied strength
	Name and address of API manufacturer.	M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 18 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: (CKTT/18001, CKTT/18002, CKTT/18003)
	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 product that is Toradol 60mg/2ml Injection by M/s Roche by performing quality tests (physical appearance, Identification, Assay, pH, sterility, bacterial endotoxin).
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, solution stability, linearity, range, Intermediate precision, repeatability, accuracy, robustness, LOD and LOQ.

STABILITY STUDY DATA

Manufacturer of API	M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India.		
API Lot No.	KTT/1002501		
Description of Pack (Container closure system)	2ml ampoule packed in foil in bleach board unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000 injection	1000 injection	1000 injection
Manufacturing Date	20-08-2020	25-08-2020	27-08-2020

Date of Initiation	22-08-2020	26-08-2020	28-08-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 0057/U2/E/19-20 dated 17-02-2020 for import of 0.8725Kg of Ketorolac Tromethamine (Batch No# KTT/1002501) from M/*s Vasudha Pharma Chem Limited, Unit-I Plot No. 37/A, 38, 39 A&B, Phase-I IDA Jeedimetla Hyderabad-500055 Telangana India* in name of M/s Wilshire Laboratories (Pvt.) Ltd attested by AD (I&E) DRAP Lahore dated 28-02-2020. ***Address of* M/*s Vasudha Pharma Chem Limited is different from that given in section 3.2.S.2***
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	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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
	60mg/2ml is administered by IM only
1.2	• The firm submitted photocopy of receipt of fee ***Rs. 20,000/-*** submitted ***dated 24-04-2019***
	• Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or Submit differential fee as the applied product is a new formulation (strength)
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.5.5	• Submit correct Pharmacological class of the drug substance with proper reference
1.6.5	• Submit Name and address of drug substance manufacturer
	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
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) ketorolac trimethylamine is submitted.
	• Clarification is required as drug substance manufacturer has mentioned the name of drug substance in batch analysis as ketorolac tromethamine while you have mentioned ketorolac triethylamine
	• Drug product manufacturer has not performed the Tromethamine Test for drug substance in batch analysis as recommended by USP
	• COA of drug substance from drug substance manufacturer is submitted from *M/s Vasudha Pharma Chem Limited, unit-I Plot No. 39, A&B, Phase-I IDA Jeedimetla Hyderabad-500055 Telangana India* while drug substance manufacturer details provided in section 3.2.S.2 is *M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India, clarify*
3.2.P.2	• Justify the role of Ethyl alcohol as preservative in the applied formulation.
	• Firm shall submit the image/picture/snapshot of 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 No# and expiry date of innovator/reference/comparator product in the section 3.2.P.2.2.1 (Formulation Development) of form 5F
3.2.P.3.3	• Justify the performance of terminal sterilization by autoclave since reference product review document does not recommend terminal sterilization.
3.2.P.5	• Justification is required for preparing different concentration of stock solution and standard solution in assay analytical method from that recommended by USP. • Justification is required for using internal standard in assay method which is not recommended by USP • Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not included in specification • The manufacturing date of trial batches mentioned in batch analysis (11-08-2020, 25-08-2020, 25-08-2020) is different from that mentioned in submitted BMR (20-08-2020, 25-08-2020, 27-08-2020), clarify • Clarification is required as you have mentioned the generic name of drug substance in batch analysis as ketorolac triethylamine instead of ketorolac tromethamine.
3.2.P.8	• As per submitted invoice drug substance is imported from M*/s Vasudha Pharma Chem Limited, Unit-I Plot No. 37/A, 38, 39 A&B, Phase-I IDA Jeedimetla Hyderabad-500055 Telangana India* while drug substance manufacturer details provided in section 3.2.S.2 is *M/s Vasudha Pharma Chem Limited, Unit-III Plot No. 23&24, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam-531019, Andra Pradesh, India, clarify*

Decision: Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting fir reply.

899.	Name, address of Applicant / Marketing Authorization Holder	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No. 4, Pharma City, 30-Km Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No. 4, Pharma City, 30-Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-22/2001-Lic (Vol-II) dated 07-06-2021 which specifies Eye Drops Section (General) and Eye Drops Section (Steroid)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy.No. 1895 dated 20-01-2022
	Details of fee submitted	Rs. 30,000/- dated 24-05-2021 (Deposit slip#3141834076)
	The proposed proprietary name / brand name	Venac Forte 0.3% Eye Drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Suspension Contains: Nepafenac…….3mg
	Pharmaceutical form of applied drug	Eye Drops suspension
	Pharmacotherapeutic Group of (API)	NSAIDs
	Reference to Finished product specifications	Manufacturer Specifications
	Proposed Pack size	3ml
	Proposed unit price	Rs 665.00/-

	The status in reference regulatory authorities	ILEVRO 0.3%, ophthalmic suspension, USFDA Approved.
	For generic drugs (me-too status)	Curanep Forte Eye Drops by M/s The Schazoo Pharmaceutical, (Reg. No. 107144)
	Name and address of API manufacturer.	M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, 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 of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, batch analysis and justification of specification, container closure system of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not submitted
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Nepatek 0.3% eye drops by M/s Innvotek Pharmaceuticals Islamabad by performing quality tests (Physical appearance, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, accuracy, linearity, precision, robustness, system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China		
API Lot No.	202080901		
Description of Pack (Container closure system)	LDPE bottles with nozzle and cap of 3ml		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 bottles	2000 bottles	2000 bottles
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	20-10-2020	20-10-2020	20-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted only stability summary data sheets.
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
1.1	• Clarification is required as the fee is submitted almost 08 months before the R&I date of submitted application.
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
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	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both drug substance manufacturer and Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Sterility test for drug substance is not performed in batch analysis by drug product manufacturer as recommended by drug substance manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.S.8	• Stability study data of drug substance from drug substance manufacturer till claimed shelf life is not submitted
3.2.P.	• Submit module 3 drug product part section 3.2.P.1 and 3.2.P.2 as per CTD guidance document • Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, in pharmaceutical equivalence studies • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • Justify why complete testing has not been performed in pharmaceutical equivalence studies as per finished product specifications
3.2.P.3	• Justification is required as the manufacturing procedure of the applied product does not contain sterilization process
3.2.P.5	• Justification is required for not including test for benzalkonium chloride identity, benzalkonium chloride assay, edetate disodium identity, edetate disodium assay, osmolality, redispersibility, viscosity, particle size distribution and endotoxin content in finished product specification as recommended by innovator product review document. • The limit of pH test (pH 7.0-8.0) is different than that recommended by innovator product review document (pH 6.8). • The results of assay test are more than that recommended by innovator product review document (7.75, 7.69, 7.72) • Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not included in specification

3.2.P.6	• COA of secondary reference standard is submitted from M/s Precise Chem Pharma Pvt. Ltd India while drug substance manufacturer as per section 3.2.S.2 is M/s Hangzhou Zhongchang Scientific Co., Ltd., E/19 Tianyuan Mansion, No. 508, Wensan Road, Hanzghou, China, Clarify
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP • Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA is not submitted • Justification is required as the stability study has not been performed as per the stability conditions recommended by ICH Q1A (R2) 2.2.7.3. for Drug products packaged in semipermeable containers • Justification is required as tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> is not performed in stability studies • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted

Decision: Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting fir reply.

900.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on 21-05-2019 based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-12/89-Lic (Vol-II) dated 23-07-2012 which specifies Lyophilized Vials (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. 2523 dated 26-01-2022
	Details of fee submitted	PKR 30,000/-: dated 20-12-2021 (Deposit Slip#1799701158)
	The proposed proprietary name / brand name	Voricol 200mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Voriconazole lyophilized powder…….200mg
	Pharmaceutical form of applied drug	Lyophilized powder
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	In-House specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VFEND 200mg lyophilized powder for injection, USFDA approved
	For generic drugs (me-too status)	V.Zde 200mg/Vial Injection by M/s Neutro Pharma (Reg. No. 097657)

	Name and address of API manufacturer.	M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District) Telangana State, 502319 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, 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 study.
	Module III (Drug Substance)	Firm has submitted detailed data of drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{O} \pm 2^{O}$ C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{O}C ± 2^{O} C / 65% ± 5% RH for 60 months. (Batches: VR0411003, VR0411004, VR0411005)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Vfend injection by M/s Pfizer by performing quality tests (Identification, pH, Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, robustness, LOD, LOQ, system suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District) Telangana State, 502319 India.
API Lot No.	VZFP21019
Description of Pack (Container closure system)	30ml transparent type I tubular Glass vial 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: 0, 3 months Accelerated: 0, 3 months

Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	VOR 21-082	VOR 21-083	VOR 21-084
Batch Size	200 Vials	200 Vials	200 Vials
Manufacturing Date	22-07-2021	23-07-2021	24-07-2021
Date of Initiation	25-7-2021	25-7-2021	25-7-2021
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)	NA
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 in the name of M/s Lee Pharma Limited., Survey No. 10/G-1, Gaddapotharam (Village), Jinnaram (Mandal), Sangareddy (District) Telangana State, 502319 India issued by Drugs Control Administration Government of Telangana valid upto 16-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 1108/LP/2021-22 dated 18-06-2021 for import of 1.5kg of Voriconazole EP (Batch No# VZFP21019) in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 06-07-2021. Firm has also submitted copy of form 6 dated 06-07-2021 for import of 1.5kg of Voriconazole EP in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 06-07-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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 upto 03 months is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 03 months is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.6.5	• Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Clarification is required for use of placebo in specificity test of method verification studies for drug substance
3.2.P.1.3	• Reference shall be provided for recommending the use of 0.9% sodium chloride as diluent for reconstitution
3.2.P.5	• Justification is required for not including the test for water content, appearance and clarity of reconstituted solution, colour of solution, reconstitution time, uniformity of dosage units, osmolality, and particulate contamination in finished product specification as recommended by EMA public assessment report. • Justification is required for not including the test for filled weight in finished product specifications • Submit reference for selecting the limits of pH test in finished product specifications
3.2.P.6	• The submitted COA of Reference Standards or Materials states that it is valid upto 01-08-2021. Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the 3rd month time point and 6th month time stability study have been performed on October 2021 (10-2021) and January 2022 (01-2022).

3.2.P.8	• Submit details of minimum handling capacities of the equipment used in manufacturing of trial batches • Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 06 months is not submitted

Decision: Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting fir reply.

901.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	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 GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018 which specifies Tablet section (General/Antibiotic)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2367 dated 25/01/2022
	Details of fee submitted	PKR 30,000/-: dated 15/09/2021 (Deposit Slip# 87660456)
	The proposed proprietary name / brand name	**Empawrd-M 12. 5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin (In-House)……..……12.5mg Metformin HCl (USP)…….…...500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetics
	Reference to Finished product specifications	Manufacturer specifications
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5 mg/1000 mg) film-coated tablet USFDA approved
	For generic drugs (me-too status)	Xenglu-Met 12.5/500mg Tablets by M/s Hilton Pharma (Reg#093067)
	Name and address of API manufacturer.	**Empagliflozin:** M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fumeng County, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **<u>Metformin HCl:</u>** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410029, MEF/1410028, MEF/1410027) **Empagliflozin:** ***Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months*** Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20160606, 20161017, 20161219)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, 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 that is Empaa-M 12.5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). CDP has been performed against the same brand that is Empaa M 12.5/500 mg Tablet by M/s Weatherfolds Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, LOD, LOQ.

STABILITY STUDY DATA	
Manufacturer of API	**<u>Empagliflozin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India
API Lot No.	**Metformin HCl:** MEF/18091912 **Empagliflozin:** E-20181027-D02-E06-01
Description of Pack (Container closure system)	Not submitted
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	900 tab	900 tab	900 tab
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	28/08/2020	28/08/2020	28/08/2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, Fluoride Industrial Park, Fuxin City, Liaoning Province - 123000, China issued by Fuxin Food and Drug Administration China valid upto 27-09-2020. Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., China valid upto 20-12-2022. **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 09-01-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice No. HN190108-C dated 08-01-2019 for import of 0.41Kg of Empagliflozin (Batch No# E-20181027-D02-E06-01) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. Firm has also submitted copy of form 6 dated 23-01-2019 for import of 0.41Kg of Empagliflozin in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. **Metformin HCl:** Firm has submitted copy of invoice No. EXP/1678/18-19 dated 21-11-2018 for import of 500Kg of Metformin HCl (Batch No# MEF/18091912) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 05-12-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Fir has submitted data of stability batches supported by attested respective documents like chromatograms, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted

1.4.1.	• The applied drug product is a generic drug product while you have applied for a new drug product, clarify
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for Empagliflozin and Metformin issued by relevant regulatory authority of country of origin is required • Address of M/s Aarti drugs Limited in submitted application is different than that mentioned in GMP certificate, clarify
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.3	• Details of Elucidation of Structure and other Characteristics for metformin HCl shall be submitted • List of Drug Substance / API-related impurities and process-related impurities metformin HCl shall be submitted along with acceptance limits
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by both drug substance manufacturer and Drug Product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin 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 Metformin HCl and Empagliflozin shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as recommended by USP. • Justification is required for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as recommended by USP • Justification is required for not performing test for identification and residue on ignition for drug substance empagliflozin by drug product manufacturer as recommended by drug substance manufacturer. • Unsigned copy of batch analysis of drug substance empagliflozin by drug product manufacturer is submitted
3.2.P.2	• Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • Submit detailed CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters used and f2 factor calculation
3.2.P.5	• Justification is required for not including test for content uniformity for empagliflozin in finished product specifications as recommended by innovator product review document • Justification is required for not including the test for assay in finished product specifications • Justification is required for not mentioning the time for dissolution studies in finished product specifications as recommended by innovator product review document • Detailed analytical procedures used for testing the drug product shall be provided. • Results for specificity test is not submitted in method validation studies • Justification is required for not performing test for content uniformity in batch analysis as recommended by innovator product review document
3.2.P.6	• Detail of the container closure systems of drug substance is submitted instead of drug product
3.2.P.8	• Submit complete analytical record of stability study including summary data sheets, COA, Raw data sheets, and chromatograms • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted
Decision: Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting fir reply.	

Case No. 03; New application for registration of Human drugs with stability study data on Form 5D on export facilitation

Assistant director PR-I/EFD vide letter No.F.1-6/2019-PR-I (EFD dated 06-10-2022 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis

to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

902.	Name and address of manufacturer / Applicant	M/s Pharmevo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Velix 5mg Tablet
	Composition	Each film coated tablet contains: Vortioxetine hydrobromide eq. to Vortioxetine…….5mg
	Diary No. Date of R& I & fee	Dy. No. 4029 dated 21/04/2017; PKR 50,000/- dated 20/04/2017 ***Duplicate Dossier (R&I verified)***
	Pharmacological Group	Anti- Depression
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX 5mg film coated tablet USFDA Approved.
	Me-too status (with strength and dosage form)	Vorneu Tablet 5mg by M/s Hilton Pharma (Reg. No#107776)
	GMP status	Firm has submitted cGMP certificate issued on 17th September, 2020 based on inspection conducted on 16th September 2020.
	Remarks of the Evaluator :	

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huainan, Jiangsu China		
API Lot No.	3804-201807001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19PD-2676-03-T	19PD-2677-04-T	19PD-2678-05-T
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	10-05-2019	10-05-2019	10-05-2019
No. of Batches	03		
Date of Submission	(Dy. No 10997) 09-04-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their product conducted by the panel on the basis of which Registration Board in 293rd meeting dated 6th-8th January, 2020 decided to approve registration of Empagin XR Tablets 5/1000mg, Empagin XR Tablets 10/1000mg, Empagin XR Tablets 12.5/1000mg, Empagin XR Tablets 25/1000mg. Inspection date: 05th December, 2019 The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. • Audit Trail on the testing reports are available. • The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All chambers are properly qualified. All chambers are provided with continuous power supply and data loggers for continuous monitoring.

2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.
3	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted method used for analysis of API from both API Manufacturer and Finished Product manufacturer
4	Stability study data of API from API manufacturer	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 36 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (X231303161, X231303231, X231303301)
5	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 in the name of M/s Jiangsu Yongan Pharmaceutical Co., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China ***issued by Huaian Pharmaceutical Industry Association No. 168, West Chaoyang Road, Qingpu Industrial Park, Huaian, Jiangsu*** valid upto 14-01-2024.
6	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. ZY18083101G/W dated 31-08-2018 for import of 900g of Vortioxetine Hydrobromide (Batch No# 3804-201807001) in name of M/s PharmEvo (Pvt) Ltd attested by AD (I&E) DRAP Karachi dated 24-09-2018. Firm has also submitted copy of form 6 dated 24-09-2018 for import of 900g of Vortioxetine Hydrobromide in name of M/s PharmEvo (Pvt.) Ltd attested by AD (I&E) DRAP Karachi dated 24-09-2018.
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted
9	Drug-excipients compatibility studies (where applicable)	The firm submitted that they used same excipients in their product as used by innovator product.
10	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record. Details are as under: Batch no. / Batch Size / Mfg. Started 19PD-2676-03-T / 2500 / 05-2019 19PD-2677-04-T / 2500 / 05-2019 19PD-2678-05-T / 2500 / 05-2019
11	Record of comparative dissolution data (where applicable)	Firm has submitted Comparative dissolution study of their product with innovator Brand Brintellix 5 mg film-coated tablets by M/s H. Lundbeck A/S, Denmark. The details are as follows: Feature / Reference Product / Product of PharmEvo Brand Name / Brintellix 5 mg film-coated tablets / Velix 5mg Tablet Batch No. / 2584289 / 19PD-2676-03-T 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 The release of both the reference product and test product is more than 85% in in both acid media pH 1.2 and acetate media pH 4.5 so values of f2 is not calculated. The value of f2 factor calculated is more than 50% in phosphate buffer.
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of 03 batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
13	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

14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. TRINTELLIX is not approved for use in pediatric patients.

Observations	Response
• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required • Drug product manufacturer has not performed test for polymorph confirmation, particle size distribution, bromine content in COA although performed by drug substance manufacturer, clarify • Justify the hold time during different steps of manufacturing processes involved in applied formulation • Justification is required for dissolution specifications NLT 80% (Q); (Q+5=85%) in 30min instead of NLT Q in 20min as recommended by innovator product review document	• The firm has submitted copy of DML # (Su 20160324) of M/s Jiangsu Yongan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China valid upto December 06, 2025. • The firm has submitted specification and method of analysis, as well as certificate of analysis including the complete test (i.e., polymorph confirmation, particle size distribution and bromine content), of the drug substance manufacturer as well as finished product manufacturer. • The firm submitted that since all testing parameters were within the specifications at the time of the initial, 3rd and 6th month stability testing, it is evident that the product was kept in the recommended storage conditions during the manufacturing process • The firm submitted that the Center for Drug Evaluation and Research recommends dissolution specifications of NLT 80% (Q); (Q+5=85%) in 30 minutes based on the chemistry review.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**

BOX WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. TRINTELLIX is not approved for use in pediatric patients.

Case No. 04; New application for registration of Human drugs on Form 5-F on export facilitation

Assistant director PR-I/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 29-12-2022 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

903.	Name, address of Applicant / Marketing Authorization Holder	M/s Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta road, Islamabad, Pakistan
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta road, Islamabad, Pakistan
	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 GMP certificate issued on 17-07-2019 based upon inspection conduct 21-05-2019, valid upto 20-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-21/2012-Lic (Vol-I) dated 09-04-2020 which specifies Tablet Section (General)-Revised
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17602 dated 16/06/2022
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022 (Deposit slip#1655993562)
	The proposed proprietary name / brand name	**Moxilox 400 mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin hydrochloride equivalent to moxifloxacin …….400 mg.
	Pharmaceutical form of applied drug	Film coated tablets
	Pharmacotherapeutic Group of (API)	Fluoroquinolones antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avelox 400mg film coated tablets USFDA Approved
	For generic drugs (me-too status)	Moxiget 400mg Tablet by M/s Getz Pharma (Reg#47117)
	Name and address of API manufacturer.	M/s Vital Laboratories Pvt. Ltd., Plant: II, Plot No. 1710 & A1/2208 , GIDC Estate, Phase III Vapi – 396 195 Gujarat, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 of Drug Substance (Conditions & duration of 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: (MOX1607001, MOX1608002, MOX1608003)
	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 innovator brand that is Avelox 400mg tablets by performing quality tests (Appearance, Identification, Disintegration, Dissolution, Assay)., CDP has been performed against the same brand that is Avelox 400mg tablet by in Acid media (pH 1.2) acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 factor are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including linearity and range, accuracy and recovery, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vital Laboratories Pvt. Ltd., Plant: II, Plot No. 1710 & A1/2208 , GIDC Estate, Phase III Vapi – 396 195 Gujarat, India.		
API Lot No.	MOX2010021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	Mox(400)-ST-001	Mox(400)-ST-002	Mox(400)-ST-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate in the name of M/s Vital Laboratories Pvt. Ltd., Plot No. 1710, GIDC Estate, Phase III Vapi – 396 195, District Valsad, Gujarat State, India issued by Food & Drugs Control Administration Gandhinagar India valid upto 16-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. HHM/2122/00063 dated 08-06-2021 for import of 2.5kg of Moxifloxacin HCl (Batch No# MOX2010021) in name of M/s Herbion Pakistan Pvt. Ltd., attested by AD (I&E) DRAP Islamabad dated 02-07-2021. Firm has submitted copy of clearance certificate including details of invoice No. HHM/2122/00063 dated 08-06-2021 for import of 2.5kg of Moxifloxacin HCl (Batch No# MOX2010021) in name of M/s Herbion Pakistan Pvt. Ltd., attested by AD (I&E) DRAP Islamabad dated 02-07-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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 upto 03 months is submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 03 months is submitted

Remarks of Evaluator [xi]:

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted GMP certificate issued on 17-11-2022 based upon inspection conduct 04-07-2022.
3.2.S.4	• Justification is required as drug substance manufacturer has submitted specifications as per EP while drug product manufacturer has submitted specification as per USP. • Justification is required for using different chromatographic (flow rate 0.9ml/min, injection volume 25ul, column 4mx25cm, 55-um packing L11) conditions than recommended by drug substance manufacturer (flow rate 1.3ml/min, injection volume 10ul, column 25cmx4m, 5-um) • Justification is required as the drug substance manufacturer and drug product manufacturer has not performed the test for enantiomeric purity in batch analysis • Drug product manufacturer has not performed the test for appearance of solution in batch analysis	• The specifications Doc. No. STM/RMS/160, effective date 09-11-2021, entitle as "Specification and Testing Method for Moxifloxacin Hydrochloride" is referenced as USP 2020 and the analysis is performed as per stated pharmacopoeia. Further to add the drug manufacturer may use specifications of raw materials as mentioned in any official monograph. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-q7-good-manufacturing-practice-active-pharmaceutical-ingredients-questions-answers_en.pdf "As per ICH Guide lines, [ICH Q7, 7.31], A raw material supplier's Certificate of Analysis (CoA) may not necessarily align with the user's specifications and submitted referenced documents. • Since we have used specifications and testing method as per USP 2020, so all the chromatographic conditions are in compliance with mentioned pharmacopoeia. • The organic impurities including enantiomeric purity are performed as mentioned in USP 2020. The COA, raw data calculation sheet, chromatogram and audit trail is submitted. • The firm submitted that Since "test for appearance of solution" is not mentioned in USP 2020 and our analytical results are in compliance with above mentioned pharmacopoeia.
3.2.P.5	• Justification is required for not including the dissolution test in finished product specifications as recommended by USP. • Analytical method for dissolution test is not submitted • Justification is required for not mentioning the time point for dissolution test in batch analysis	• The firm submitted that although we have conducted dissolution test of finished product at all stages, where required and is part of our approved specifications and test method and submitted revised specification containing dissolution test • The signed and stamped document of Specifications & Testing Method for Moxifloxacin 400mg Tablets including Dissolution test is submitted • The firm submitted that sampling time point for dissolution test is 30 minutes, the same is mentioned in revised approved specification on page number 8 of 17 and in batch analysis report and as mentioned in USP 2020.
3.2.P.8	• Submit system generated UV spectra of dissolution test at all-time point of stability study wherein details of time and date shall be evident along with raw data sheets. • Submit stability study data of applied product at 6th month time point	• The individual system generated UV Spectra of each sample, showing sample name, analyst name, batch number, date and time is clearly mentioned along with already provided stacking format report. All UV Spectra (Individual spectra) for each time point

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 06 months is not submitted	including initial, 3rd, 6th, 9th and 12th month is submitted. • The 6th month stability data of product is submitted. • The compliance record of HPLC Software 21CFR & Audit trail reports on product testing up to 06 months is submitted. • The record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) up to 6th months is submitted.

Decision: Approved. Registration letter will be issued after submission of Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **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.**

904.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20199 dated: 15/07/2022
	Details of fee submitted	Copy of fee challan of another strength is submitted
	The proposed proprietary name / brand name	**Daplozmet XR 5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….5mg Metformin hydrochloride (Extended release) ……..…500mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 5/500mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 5/500 XR Tablet by M/s CCL Pharmaceuticals (Reg#110985)
	Name and address of API manufacturer.	**Dapagliflozin:**

		Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** 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 of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, 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 has been established against the innovator brand that is XIGDUO XR 5/500mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the same brand that is XIGDUO XR 5/500mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.
STABILITY STUDY DATA		
Manufacturer of API		**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:**

	Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	RD-21320	RD-21321	RD-21305
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	08-01-2022	08-01-2022	08-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D) Dated 22-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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 upto 03 months is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Fee challan for applied product is not submitted. Submit original fee challan submitted for applied product
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document
3.2.P.2	• Justification is required for using 5% (0.307mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted

Decision: Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting fir reply.

905.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20201 dated: 15/07/2022
	Details of fee submitted	Copy of fee challan of another strength is submitted
	The proposed proprietary name / brand name	**Daplozmet XR 5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….5mg Metformin hydrochloride (Extended release) ……1000mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	XIGDUO XR 5/1000mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 5/1000 XR Tablet by M/s CCL Pharmaceuticals (Reg# 110626)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** 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 of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, 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 has been established against the innovator brand that is XIGDUO XR 5/1000mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the brand that is XIGDUO XR 5/1000mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.
STABILITY STUDY DATA		

Manufacturer of API	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21281	RD-21226	RD-21168
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	10-2021	09-2021	08-2021
Date of Initiation	06-11-2022	06-11-2022	06-11-2022
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D Dated 22-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [xi]:

Section	Observations
1.1	• Fee challan for applied product is not submitted. Submit original fee challan submitted for applied product
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee
1.5.6	• Clarification is required as you have claimed Manufacturer's Specifications / Innovator specifications?
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document
3.2.P.2	• Justification is required for using 5% (0.307mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies
3.2.P.8	• Justification is required since submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed (22-11-2021) subsequent to the initiation of stability study (6-11-2021) for all batches

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case No. 05: Deferred cases of form 5F (Export Facilitation):

906.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	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 13-05-2019 based on inspection conducted on 30-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal letter No.F.1-8/84-Lic(Vol-V) dated 08-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1308 dated 14-01-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021 (Slip#4452496739)
	The proposed proprietary name / brand name	**Gablin CR 82.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pregabalin……..…82.5mg
	Pharmaceutical form of applied drug	Pink colored, oblong biconvex film coated tablet

	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) by USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 of Drug Substance (Conditions & duration of 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: (PRG/P0904005, PRG/P0904006, PRG/P0904007)
	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	Pharmaceutical Equivalence have been established against the innovator Lyrica CR 82.5mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017, by performing quality tests (Description, Identification, Assay, Dissolution). CDP has been performed against the same brand that is Lyrica CR 82.5mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017 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	Analytical method validation report is not submitted

STABILITY STUDY DATA	
Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
API Lot No.	PRGH/P2012004D
Description of Pack (Container closure system)	Printed Alu-Alu blister packed in bleach board unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PGA T2-21	PGA T3-21	PGA T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-2021	05-2021	05-2021
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License retention certificate dated 29-02-2020 of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025. Firm has submitted cGMP certificate dated 20-10-2020 of M/s Kopran Research Laboratories Limited., India., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP-393 dated 28-12-2020 for import of 100kg of Pregabalin (Batch# PRGH/P2012004D) in name of M/s CCL Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 04-01-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted DML renewal Inspection report conducted on 14.09.2020, 15.09.2020 and 21.10.2020 and panel has recommended renewal of DML for following sections; Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid). • Firm has submitted Letter No. 8194/2022-DRAP (Addl.Dire) dated 07.07.2022 from Additional Director DRAP Lahore which states that; "The Firm has applied for GMP Inspection. The application is under process at DRAP Office and inspection will be done as per availability of Area FID. The firm's last GMP status is Compliant / Good.

1.5.2	• Clarification is required as you have applied for film coated tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	The firm submitted that applied formulation is as per reference formulation i.e., film coated extended release that is evident from dissolution results. Label claim for products is: Each film coated extended-release tablet contain: Pregabalin…….82.5mg.
3.2.S.4	• Justification is required for claiming in-house specifications for drug substance by drug substance manufacturer and drug product manufacturer as the monograph for applied drug substance is available in pharmacopeia (BP, USP) • Justification is required for using in-house analytical method for drug substance by drug substance manufacturer and drug product manufacturer as the analytical method for applied drug substance is available in pharmacopeia (BP, USP) • Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the COA of Reference Standards or Materials states that it is to be used before 19-03-2016, while manufacturing date of drug substance as per submitted COA is Dec 2020.	• The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house specs. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and drug product manufacturer are in process of shifting the specification as per USP Monograph. • The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house analytical method. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and Drug product manufacturer are in process of shifting the analytical method as per USP Monograph. • The firm submitted that provided COA of reference standard was taken from DMF. COA of working standard used for the analysis of drug substance is submitted which states that it is to be used before 11-07-2021**.**
3.2.P.2	• Submit evidence for storing samples prepared for compatibility study at 60˚C ± 3˚C / 75% ± 5%RH for 10 days	***The firm submitted record of data logger for temperature and humidity monitoring for sample prepared for compatibility study***
3.2.P.5	• Justification is required for changing wavelength during assay procedure in analytical method from 300nm to 210nm after 4.5 minutes • Submit analytical method validation report for the applied product	• The firm submitted that in product test method 300nm is used to suppress blank peak and the principal peak of pregabalin is around 5.1 that's why wavelength is changed at 210nm from 4.5min to onward. • Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, LOD & LOQ, robustness and solution stability and system suitability studies.
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the COA of Reference Standards or Materials states that it is to be used before 11-07-2021, while manufacturing date of drug product as per submitted COA is April 2021 and 3rd month time point and 6th month time stability study are due on July 2021 (07-2021) and October 2021 (10-2021).	• The firm submitted that same reference standard was used for analysis of drug product as the sequence / chromatograms against this standard was saved during trial analysis and same sequence / chromatograms of standard was used at 3rd and 6th Month stability study time point for analysis of drug product. It is to submit that the Reference Standards or Materials used for test and analysis of drug product was expired at 6th month time point (October 2021 (10-2021)) of stability study.
3.2.P.8	• The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	• The firm submitted that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. So in chromatogram starting wavelength is mentioned which is 300nm.

	• Clarification is required for not including the results and calculation details for content uniformity test in raw data sheet at initial time point of stability study • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula shall be submitted • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has submitted results and calculation details for content uniformity test in raw data sheet at initial time point of stability study. • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula is submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Previous Decision (324-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that we have also used the reference standard submitted as Annex-1 for the analysis of Drug product at 6th Month Stability study time point. Moreover, as we were in phase of shifting the Specs of Raw Material from In-house to USP so we have also used the Reference standard involved in Specification shifting attached as Annex-1. We are submitting the following Supporting documents. 1) Raw Material Test Method 2) COA of Raw Material 3) Verification of Analytical Method 4) COA of Reference Standard used in shifting the specification.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The firm submitted that in dissolution chromatograms you can see at 210nm is the main peak of pregabalin, 300nm wavelength is not interfaring with pregabalin response, specificity chromatogram is submitted in AMV report. Method trail is also attached.
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that as already communicated that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. Method trail is also submitted. In Chromatograms starting wavelength is mentioned which is 300nm.

Decision: Deferred for scientific justification of following points:

- **Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.**
- **Use of dual wavelengths for the analysis of single drug substance containing formulation.**
- **The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required**

907.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	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 13-05-2019 based on inspection conducted on 30-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal letter No.F.1-8/84-Lic(Vol-V) dated 08-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1309 dated 14-01-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021 (Slip#20328944978)
	The proposed proprietary name / brand name	Gablin CR 165mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pregabalin……..…165mg
	Pharmaceutical form of applied drug	Light brown colored, oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) by USFDA Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 of Drug Substance (Conditions & duration of 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: (PRG/P0904005, PRG/P0904006, PRG/P0904007)

	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	Pharmaceutical Equivalence have been established against the innovator Lyrica CR 165mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017, by performing quality tests (Description, Identification, Assay, Dissolution). CDP has been performed against the same brand that is Lyrica CR 165mg Tablet distributed by M/s Parke-Davis Division of Pfizer Inc. NY, NY 10017 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	Analytical method validation report is not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	PRGH/P2012004D		
Description of Pack (Container closure system)	Printed Alu-Alu blister packed in bleach board unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PGB T2-21	PGB T3-21	PGB T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	05-2021	05-2021	05-2021
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License retention certificate dated 29-02-2020 of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025. Firm has submitted cGMP certificate dated 20-10-2020 of M/s Kopran Research Laboratories Limited., India., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP-393 dated 28-12-2020 for import of 100kg of Pregabalin (Batch# PRGH/P2012004D) in name of M/s CCL Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 04-01-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

	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
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted DML renewal Inspection report conducted on 14.09.2020, 15.09.2020 and 21.10.2020 and panel has recommended renewal of DML for following sections; Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid). • Firm has submitted Letter No. 8194/2022-DRAP (Addl.Dire) dated 07.07.2022 from Additional Director DRAP Lahore which states that; "The Firm has applied for GMP Inspection. The application is under process at DRAP Office and inspection will be done as per availability of Area FID. The firm's last GMP status is Compliant / Good.
1.5.2	• Clarification is required as you have applied for film coated tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	The firm submitted that applied formulation is as per reference formulation i.e., film coated extended release that is evident from dissolution results. Label claim for product is: Each film coated extended-release tablet contain: Pregabalin…….165mg.
3.2.S.4	• Justification is required for claiming in-house specifications for drug substance by drug substance manufacturer and drug product manufacturer as the monograph for applied drug substance is available in pharmacopeia (BP, USP) • Justification is required for using in-house analytical method for drug substance by drug substance manufacturer and drug product manufacturer as the analytical method for applied drug substance is available in pharmacopeia (BP, USP) • Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the COA of Reference Standards or Materials states that it is to be used before 19-03-2016, while manufacturing date of drug substance as per submitted COA is Dec 2020.	• The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house specs. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and drug product manufacturer are in process of shifting the specification as per USP Monograph. • The firm submitted Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house analytical method. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and Drug product manufacturer are in process of shifting the analytical method as per USP Monograph. • The firm submitted that provided COA of reference standard was taken from DMF. COA of working standard used for the analysis of drug substance is submitted which states that it is to be used before 11-07-2021**.**
3.2.P.2	• Submit evidence for storing samples prepared for compatibility study at 60˚C ± 3˚C / 75% ± 5%RH for 10 days	***The firm submitted record of data logger for temperature and humidity monitoring for sample prepared for compatibility study***

3.2.P.5	• Justification is required for changing wavelength during assay procedure in analytical method from 300nm to 210nm after 4.5 minutes • Submit analytical method validation report for the applied product	• The firm submitted that in product test method 300nm is used to suppress blank peak and the principal peak of pregabalin is around 5.1 that's why wavelength is changed at 210nm from 4.5min to onward. • Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, LOD & LOQ, robustness and solution stability and system suitability studies.
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3.2.P.8	• The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required • Clarification is required for not including the results and calculation details for content uniformity test in raw data sheet at initial time point of stability study • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula shall be submitted • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm submitted that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. So in chromatogram starting wavelength is mentioned which is 300nm. • Firm has submitted results and calculation details for content uniformity test in raw data sheet at initial time point of stability study. • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula is submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Previous Decision (324-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that we have also used the reference standard submitted as Annex-1 for the analysis of Drug product at 6th Month Stability study time point. Moreover, as we were in phase of shifting the Specs of Raw Material from In-house to USP so we have also used the Reference standard involved in Specification shifting attached as Annex-1. We are submitting the following Supporting documents. 1) Raw Material Test Method 2) COA of Raw Material 3) Verification of Analytical Method

		4) COA of Reference Standard used in shifting the specification.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The firm submitted that in dissolution chromatograms you can see at 210nm is the main peak of pregabalin, 300nm wavelength is not interfaring with pregabalin response, specificity chromatogram is submitted in AMV report. Method trail is also attached.
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that as already communicated that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. Method trail is also submitted. In Chromatograms starting wavelength is mentioned which is 300nm.

Decision: Deferred for scientific justification of following points:

- **Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.**
- **Use of dual wavelengths for the analysis of single drug substance containing formulation.**
- **The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required**

908.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore.
	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 13-05-2019 based on inspection conducted on 30-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML renewal letter No.F.1-8/84-Lic(Vol-V) dated 08-06-2022 which specifies Tablet section (General).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1310 dated 14-01-2022
	Details of fee submitted	Rs.75,000/- dated 30-12-2021 (Slip#683187860)
	The proposed proprietary name / brand name	Gablin CR 330mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Pregabalin……..…330mg
	Pharmaceutical form of applied drug	Orange colored, oblong biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA CR extended-release tablets (82.5mg, 165mg, 330 mg) by USFDA Approved.
	For generic drugs (me-too status)	NA

	Name and address of API manufacturer.	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 of Drug Substance (Conditions & duration of 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: (PRG/P0904005, PRG/P0904006, PRG/P0904007)
	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.
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	Analytical method validation/verification of product	Analytical method validation report is not submitted

STABILITY STUDY DATA

Manufacturer of API	M/s Kopran Research Laboratories Limited., K4/4, Additional MIDC, Post Birwadi, Tal. Mahad, District: Raigad, Raigad 402302, Maharashtra India.		
API Lot No.	PRGH/P2012004D		
Description of Pack (Container closure system)	Printed Alu-Alu blister packed in bleach board unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PGC T2-21	PGC T3-21	PGC T4-21
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2021	04-2021	04-2021

Date of Initiation	05-2021	05-2021	05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted License retention certificate dated 29-02-2020 of M/s Kopran Research Laboratories Limited., India., issued by Food & Drugs Administration Maharashtra State India valid upto 31-03-2025. Firm has submitted cGMP certificate dated 20-10-2020 of M/s Kopran Research Laboratories Limited., India., issued by Commissioner, Food & Drugs Administration Maharashtra State India valid upto 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EXP-393 dated 28-12-2020 for import of 100kg of Pregabalin (Batch# PRGH/P2012004D) in name of M/s CCL Pharmaceuticals (Pvt.) Ltd., attested by AD (I&E) DRAP Lahore dated 04-01-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted DML renewal Inspection report conducted on 14.09.2020, 15.09.2020 and 21.10.2020 and panel has recommended renewal of DML for following sections; Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid). • Firm has submitted Letter No. 8194/2022-DRAP (Addl.Dire) dated 07.07.2022 from Additional Director DRAP Lahore which states that; "The Firm has applied for GMP Inspection. The application is under process at DRAP Office and inspection will be done as per availability of Area FID. The firm's last GMP status is Compliant / Good.
1.5.2	• Clarification is required as you have applied for film coated tablets while the reference formulation is film coated extended release tablets or revise your label claim as per reference formulation along with submission of applicable fee.	The firm submitted that applied formulation is as per reference formulation i.e., film coated extended release that is evident from dissolution results. Label claim for products is: Each film coated extended-release tablet contain: Pregabalin…….330mg.
3.2.S.4	• Justification is required for claiming in-house specifications for drug substance by drug substance manufacturer and drug product manufacturer as the monograph for	• The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house specs. Moreover,

	applied drug substance is available in pharmacopeia (BP, USP) • Justification is required for using in-house analytical method for drug substance by drug substance manufacturer and drug product manufacturer as the analytical method for applied drug substance is available in pharmacopeia (BP, USP) • Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug substance as the COA of Reference Standards or Materials states that it is to be used before 19-03-2016, while manufacturing date of drug substance as per submitted COA is Dec 2020.	Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and drug product manufacturer are in process of shifting the specification as per USP Monograph. • The firm submitted that Pregabalin Monograph has become official as of 01-Nov-2020, and the substance lot being used in developmental studies, manufactured in Dec 2020, that's why API manufacturer used in house analytical method. Moreover, Pregabalin is already inducted material for CCL. Both Drug substance manufacturer and Drug product manufacturer are in process of shifting the analytical method as per USP Monograph. • The firm submitted that provided COA of reference standard was taken from DMF. COA of working standard used for the analysis of drug substance is submitted which states that it is to be used before 11-07-2021**.**
3.2.P.2	• Submit evidence for storing samples prepared for compatibility study at 60˚C ± 3˚C / 75% ± 5%RH for 10 days	***The firm submitted record of data logger for temperature and humidity monitoring for sample prepared for compatibility study***
3.2.P.5	• Justification is required for changing wavelength during assay procedure in analytical method from 300nm to 210nm after 4.5 minutes • Submit analytical method validation report for the applied product	• The firm submitted that in product test method 300nm is used to suppress blank peak and the principal peak of pregabalin is around 5.1 that's why wavelength is changed at 210nm from 4.5min to onward. • Firm has submitted analytical method validation studies including specificity, linearity and range, accuracy, precision, LOD & LOQ, robustness and solution stability and system suitability studies.
3.2.P.6	• Clarification is required whether the same Reference Standards or Materials was used for test and analysis of drug product as the COA of Reference Standards or Materials states that it is to be used before 11-07-2021, while manufacturing date of drug product as per submitted COA is April 2021 and 3rd month time point and 6th month time stability study are due on July 2021 (07-2021) and October 2021 (10-2021).	• The firm submitted that same reference standard was used for analysis of drug product as the sequence / chromatograms against this standard was saved during trial analysis and same sequence / chromatograms of standard was used at 3rd and 6th Month stability study time point for analysis of drug product. It is to submit that the Reference Standards or Materials used for test and analysis of drug product was expired at 6th month time point (October 2021 (10-2021)) of stability study.
3.2.P.8	• The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required • Clarification is required for not including the results and calculation details for content uniformity test in raw data sheet at initial time point of stability study • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula shall be submitted • Submit Record of Digital data logger for temperature and humidity	• The firm submitted that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. So in chromatogram starting wavelength is mentioned which is 300nm. • Content uniformity for Gablin CR Tablet 330mg is performed by weight variation as per <USP 905>. • Raw data sheet for assay test with real time values for average area of sample, average area of standard, conc. of standard, conc. of sample, average weight, label claim and standard potency in calculation formula is submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

monitoring of stability chambers (real time and accelerated)

Previous Decision (324-DRB): Deferred for scientific justification of following points:

- Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.
- Use of dual wavelengths for the analysis of single drug substance containing formulation.
- The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required

Response of firm:

Sr#	Observations	Response
01	Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.	The firm submitted that we have also used the reference standard submitted as Annex-1 for the analysis of Drug product at 6th Month Stability study time point. Moreover, as we were in phase of shifting the Specs of Raw Material from In-house to USP so we have also used the Reference standard involved in Specification shifting attached as Annex-1. We are submitting the following Supporting documents. 1) Raw Material Test Method 2) COA of Raw Material 3) Verification of Analytical Method 4) COA of Reference Standard used in shifting the specification.
02	Use of dual wavelengths for the analysis of single drug substance containing formulation.	The firm submitted that in dissolution chromatograms you can see at 210nm is the main peak of pregabalin, 300nm wavelength is not interfaring with pregabalin response, specificity chromatogram is submitted in AMV report. Method trail is also attached.
03	The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required	The firm submitted that as already communicated that in product test method wavelength started from 300nm and then changed to 210nm after 4.5min. Method trail is also submitted. In Chromatograms starting wavelength is mentioned which is 300nm.

Decision: Deferred for scientific justification of following points:

- **Use of sequence / chromatograms of standard saved during initial time point analysis for the drug product analysis of 3rd and 6th Month stability study time point.**
- **Use of dual wavelengths for the analysis of single drug substance containing formulation.**
- **The wavelength mentioned in analytical procedure is 210nm for assay test while submitted chromatograms of stability study show 300nm, justification is required**

909.	Name, Address Of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle Kahuta Road Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 21-05-2019 based on inspection conducted on 23-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section letter No.F.1-12/98-Lic(Vol. II) dated 24-03-2007 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 154 dated 03-01-2022
	Details of fee submitted	PKR 30,000/-: dated 23-11-2021 (Deposit slip#148278185261)
	The proposed proprietary name / brand name	Dapa-Met 5/1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin…….5mg Metformin HCl……1000mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Dapagliflozin; Sodium-glucose co-transporter 2 (SGLT2) inhibitors Metformin; Biguanides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO (5mg/850mg; 5mg/1000mg) film coated tablet EMA Approved
	For generic drugs (me-too status)	Daplozmet 5mg/1000mg Tablets by M/s Highnoon Laboratories (Reg#96589)
	Name and address of API manufacturer.	**Dapagliflozin:** M/s Jiangsu Yungan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China **Metformin HCl:** Aarti Drugs Limited., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, 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, 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	**Dapagliflozin propanediol monohydrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 O ± 2 O C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30OC ± 2 O C / 65% ± 5% RH for 36 months (Batches: 130401, 130402, 130501) **Metformin Hydrochloride;**

		Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 O ± 2 O C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30OC ± 2 O C / 65% ± 5% RH for 48 months (Batches; MEF/1410027, MEF/1410028, MEF/1410029)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against innovator product Xigduo 5/1000mg Tablet of M/s AstraZeneca AB SE-151 85 Sodertalje - Sweden by performing quality tests (Description, identification, uniformity of dosage unit, Dissolution and Assay). CDP has been performed against the same brand that is Xigduo 5/1000mg Tablet of M/s AstraZeneca AB SE-151 85 Sodertalje - Sweden in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, accuracy, precision, linearity & range, system suitability, ruggedness, LOD, LOQ.

STABILITY STUDY DATA			
Manufacturer of API	**Dapagliflozin:** M/s Jiangsu Yungan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China **Metformin HCl:** Aarti Drugs Limited., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat India.		
API Lot No.	**Dapagliflozin Propanediol Monohydrate:** DGF-201902001 **Metformin Hydrochloride:** MEF/18122462		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	DAP-20-019	DAP-20-020	DAP-20-021
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	02-05-2020	02-05-2020	02-05-2020
No. of Batches	03		
Administrative Portion			

01	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
02	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin propanediol monohydrate:** The firm has submitted cGMP certificate to M/s Jiangsu Yongan Pharmaceutical Co., Ltd., China issued by Jiangsu Food and Drug Administration valid upto 03-03-2021 **Metformin HCl:** The firm has submitted GMP certificate for Aarti Drugs Limited India issued by Food & Drug Maharashtra State India. The certificate is valid till 01-11-2021
03	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of Form 6 for import of 200g of Dapagliflozin propanediol Monohydrate in name of M/s Bio-Labs (Pvt.) Ltd. attested by AD (I&E) DRAP Islamabad dated 01-04-2019. Firm has submitted copy of invoice for import of 200g of Dapagliflozin propanediol Monohydrate (Batch No. DGF-201902001) in name of M/s Bio-Labs (Pvt.) Ltd. attested by AD (I&E) DRAP Islamabad dated 01-04-2019. Firm has also submitted copy of clearance certificate for import of 200g of Dapagliflozin propanediol Monohydrate in name of M/s Bio-Labs (Pvt.) Ltd. attested by AD (I&E) DRAP Islamabad dated 01-04-2019. **Metformin HCl:** Firm has submitted copy of invoice No. EXP/2411/18-19 dated 21-02-2019 for import of 25kg of Metformin HCl (Batch No. MEF/18122462) in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 27-03-2019. Firm has submitted copy of clearance certificate for import of 25kg of Metformin HCl in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 27-03-2019.
04	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.
05	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing.
06	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator PEC[XI]:

Section	Observations
1.3.5	Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for dapagliflozin propanediol monohydrate and Metformin HCl issued by relevant regulatory authority of country of origin
3.2.S.4	• Justification is required for including assay test for metformin on titration method by drug product manufacturer and potentiometric method by drug substance manufacturer in analytical procedure instead of HPLC as recommended by USP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Metformin HCl for titration method is submitted.

	• Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC as recommended by USP.
3.2.P.2	Justification is required for not considering one time-point after 85% dissolution has been reached in CDP studies or the dissolution should be conducted until an asymptote (plateau) has been reached
3.2.P.5	• Justification is required for not including test for disintegration test in finished product specification as recommended by innovator product review document. • Submit numerical results for uniformity of dosage unit test in batch analysis for dapagliflozin and metformin. • Clarification is required as you have mentioned innovator specification in module 1 section 1.5.6 while bio labs specification in module 3 section 3.2.P.5 drug product specification

Previous Decision (324-DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response:

Section	Observations	Response of firm
1.3.5	Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years	Firm has submitted cGMP certificate issued on 28-02-2022 based on inspection conducted on 03-08-2021
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for dapagliflozin propanediol monohydrate and Metformin HCl issued by relevant regulatory authority of country of origin	**Dapagliflozin propanediol monohydrate:** The firm has submitted copy of DML # (Su 20160324) of M/s Jiangsu Yongan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China valid upto December 06, 2025. **Metformin HCl:** The firm has submitted cGMP certificate in name of M/s Aarti Drugs Limited India issued by Food & Drug Administration Gujarat State India. The certificate is valid till 19-03-2023
3.2.S.4	• Justification is required for including assay test for metformin on titration method by drug product manufacturer and potentiometric method by drug substance manufacturer in analytical procedure instead of HPLC as recommended by USP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Metformin HCl for titration method is submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC as recommended by USP.	• The firm submitted that in USP 41, potentiometric method was described and hence both drug substance manufacturer and drug product manufacturer used this method. HPLC method was published by USP 43 and accordingly we have revised standard analytical procedure and submitted revised analytical method. • Potentiometric method is type of titration and hence word titration was written by typographic mistake and test was performed by potentiometric method. • In USP 41, potentiometric method was described and hence method verification was performed accordingly. Updated method verification studies for drug substance as per USP 43 is submitted • The firm submitted that in USP 41, potentiometric method was described and hence drug substance manufacturer used this method. Now testing method is revised as per USP 43 monograph. New COA from API manufacturer is submitted
3.2.P.2	Justification is required for not considering one time-point after 85% dissolution has been reached in CDP studies or the dissolution should be conducted until an asymptote (plateau) has been reached	In previous practice, CDP was performed till 85% dissolution, now onward one time point after 85% dissolution will be considered for CDP studies.
3.2.P.5	• Justification is required for not including test for disintegration test in finished product specification as recommended by innovator product review document.	• The firm submitted that Disintegration test is now added in finished product specifications and in standard analytical procedure and revised specifications and standard analytical procedure is submitted

	• Submit numerical results for uniformity of dosage unit test in batch analysis for dapagliflozin and metformin. • Clarification is required as you have mentioned innovator specification in module 1 section 1.5.6 while bio labs specification in module 3 section 3.2.P.5 drug product specification	• Numerical results for uniformity of dosage unit test in batch analysis for dapagliflozin and metformin are added and new reports are submitted. • The firm has submitted revised finished product specifications indicting innovator's specifications

Decision: Approved with innovator's specifications. Registration letter will be issued after submission of Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **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.**

910.	Name, Address Of Applicant / Marketing Authorization Holder	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle Kahuta Road Islamabad.
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd., Plot No. 145 Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 21-05-2019 based on inspection conducted on 23-04-2019
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section letter No.F.1-12/98-Lic(Vol. II) dated 24-03-2007 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2035 dated 21-01-2022
	Details of fee submitted	PKR 30,000/-: dated 23-11-2021 (Deposit slip#0805662855)
	The proposed proprietary name / brand name	Dapa-Met 5/850mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin…….5mg Metformin HCl……850mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Dapagliflozin; Sodium-glucose co-transporter 2 (SGLT2) inhibitors Metformin; Biguanides
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO (5mg/850mg; 5mg/1000mg) film coated tablet EMA Approved
	For generic drugs (me-too status)	Daplozmet 5mg/850mg Tablets by M/s Highnoon Laboratories (Reg#96588)

	Name and address of API manufacturer.	**Dapagliflozin:** M/s Jiangsu Youngan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China **Metformin HCl:** Aarti Drugs Limited., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, 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, 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	**Dapagliflozin propanediol monohydrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 O ± 2 O C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30OC ± 2 O C / 65% ± 5% RH for 36 months (Batches: 130401, 130402, 130501) **Metformin Hydrochloride;** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 O ± 2 O C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30OC ± 2 O C / 65% ± 5% RH for 48 months (Batches; MEF/1410027, MEF/1410028, MEF/1410029)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against innovator product Xigduo 5/850mg Tablet of M/s AstraZeneca AB SE-151 85 Sodertalje - Sweden by performing quality tests (Description, identification, uniformity of dosage unit, Dissolution and Assay). CDP has been performed against the same brand that is Xigduo 5/850mg Tablet of M/s AstraZeneca AB

		SE-151 85 Sodertalje - Sweden in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 are in acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including specificity, accuracy, precision, linearity & range, system suitability, ruggedness, LOD, LOQ.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin:** M/s Jiangsu Yungan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China **Metformin HCl:** Aarti Drugs Limited., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat India.		
API Lot No.	**Dapagliflozin Propanediol Monohydrate:** DGF-201902001 **Metformin Hydrochloride:** MEF/18122462		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	DAP-20-016	DAP-20-017	DAP-20-018
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	26-04-2020	26-04-2020	26-04-2020
No. of Batches	03		

Administrative Portion

01	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
02	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin propanediol monohydrate:** The firm has submitted cGMP certificate to M/s Jiangsu Yongan Pharmaceutical Co., Ltd., China issued by Jiangsu Food and Drug Administration valid upto 03-03-2021 **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited India issued by Food & Drug Maharashtra State India. The certificate is valid till 01-11-2021
03	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin propanediol monohydrate:** Firm has submitted copy of Form 6 for import of 200g of Dapagliflozin propanediol Monohydrate in name of M/s Bio-Labs (Pvt.) Ltd. attested by AD (I&E) DRAP Islamabad dated 01-04-2019. Firm has submitted copy of invoice for import of 200g of Dapagliflozin propanediol Monohydrate (Batch No. DGF-201902001) in name of M/s Bio-Labs (Pvt.) Ltd. attested by AD (I&E) DRAP Islamabad dated 01-04-2019. Firm has also submitted copy of clearance certificate for import of 200g of Dapagliflozin propanediol Monohydrate in name of M/s Bio-Labs (Pvt.) Ltd.

		attested by AD (I&E) DRAP Islamabad dated 01-04-2019. **Metformin HCl:** Firm has submitted copy of invoice No. EXP/2411/18-19 dated 21-02-2019 for import of 25kg of Metformin HCl (Batch No. MEF/18122462) in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 27-03-2019. Firm has submitted copy of clearance certificate for import of 25kg of Metformin HCl in name of M/s Bio-Labs (Pvt.) Ltd., attested by AD (I&E) DRAP Islamabad dated 27-03-2019.
04	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.
05	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing.
06	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator PEC[XI]:

Section	Observations
1.3.5	Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for dapagliflozin propanediol monohydrate and Metformin HCl issued by relevant regulatory authority of country of origin
3.2.S.4	• Justification is required for including assay test for metformin on titration method by drug product manufacturer and potentiometric method by drug substance manufacturer in analytical procedure instead of HPLC as recommended by USP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Metformin HCl for titration method is submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC as recommended by USP.
3.2.P.2	Justification is required for not considering one time-point after 85% dissolution has been reached in CDP studies or the dissolution should be conducted until an asymptote (plateau) has been reached
3.2.P.5	• Justification is required for not including test for disintegration test in finished product specification as recommended by innovator product review document. • Submit numerical results for uniformity of dosage unit test in batch analysis for dapagliflozin and metformin. • Clarification is required as you have mentioned innovator specification in module 1 section 1.5.6 while bio labs specification in module 3 section 3.2.P.5 drug product specification

Previous Decision (324-DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response:

Section	Observations	Response of firm
1.3.5	Submit GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years	Firm has submitted cGMP certificate issued on 28-02-2022 based on inspection conducted on 03-08-2021
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for dapagliflozin propanediol monohydrate and Metformin HCl issued by relevant regulatory authority of country of origin	**Dapagliflozin propanediol monohydrate:** The firm has submitted copy of DML # (Su 20160324) of M/s Jiangsu Yongan Pharmaceutical CO., Ltd., No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China valid upto December 06, 2025.

		Metformin HCl: The firm has submitted cGMP certificate in name of M/s Aarti Drugs Limited India issued by Food & Drug Administration Gujarat State India. The certificate is valid till 19-03-2023
3.2.S.4	• Justification is required for including assay test for metformin on titration method by drug product manufacturer and potentiometric method by drug substance manufacturer in analytical procedure instead of HPLC as recommended by USP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Metformin HCl for titration method is submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC as recommended by USP.	• The firm submitted that in USP 41, potentiometric method was described and hence both drug substance manufacturer and drug product manufacturer used this method. HPLC method was published by USP 43 and accordingly we have revised standard analytical procedure and submitted revised analytical method. • Potentiometric method is type of titration and hence word titration was written by typographic mistake and test was performed by potentiometric method. • In USP 41, potentiometric method was described and hence method verification was performed accordingly. Updated method verification studies for drug substance as per USP 43 is submitted • The firm submitted that in USP 41, potentiometric method was described and hence drug substance manufacturer used this method. Now testing method is revised as per USP 43 monograph. New COA from API manufacturer is submitted
3.2.P.2	Justification is required for not considering one time-point after 85% dissolution has been reached in CDP studies or the dissolution should be conducted until an asymptote (plateau) has been reached	In previous practice, CDP was performed till 85% dissolution, now onward one time point after 85% dissolution will be considered for CDP studies.
3.2.P.5	• Justification is required for not including test for disintegration test in finished product specification as recommended by innovator product review document. • Submit numerical results for uniformity of dosage unit test in batch analysis for dapagliflozin and metformin. • Clarification is required as you have mentioned innovator specification in module 1 section 1.5.6 while bio labs specification in module 3 section 3.2.P.5 drug product specification	• The firm submitted that Disintegration test is now added in finished product specifications and in standard analytical procedure and revised specifications and standard analytical procedure is submitted • Numerical results for uniformity of dosage unit test in batch analysis for dapagliflozin and metformin are added and new reports are submitted. • The firm has submitted revised finished product specifications indicting innovator's specifications

Decision: Approved with innovator's specifications. Registration letter will be issued after submission of Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

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

Case No. 06; Deferred Registration Application of Human Drugs on form 5:

911.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Lesart 10/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan……40mg Amlodipine as Besylate……10mg

	Dairy No. date of R &I fee	Form-5 Dy.No 11213 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA (40/5mg, 40/10mg, 80/5mg, 80/10mg) Tablets USFDA Approved
	Me-too-status	Cresar AM Tablet 10mg/40mg by M/s Tabros Pharma (Reg#094851)
	GMP Status	
	Previous Remark of the Evaluator [XI]	• You have applied for film coated tablets while the reference formulation is bilayered tablets. Revise your label claim, formulation and manufacturing outline as per reference formulation along with submission of applicable fee. • Provide evidence of availability of bilayered compression tablet facility • Submit latest GMP inspection report conducted within last three years
	Previous Decision (DRB-322)	• Registration Board deferred the case for submission of reply to the above cited shortcomings within six months of issuance of minutes of 322nd meeting. In case Pharmaceutical Evaluation Cell does not receive any response from firm within the given time, the case will be placed before Registration Board for decision.
	Response of the firm	• The firm has revised the label claim, formulation and manufacturing outline as per reference formulation along with submission of Rs. 7500/- on deposit slip No#86422725476. The revised label claim is as under: Each Bilayered Tablet Contains: Telmisartan……40mg Amlodipine as Besylate……10mg • Evidence of availability of bilayered compression tablet facility and latest GMP inspection report conducted within last three years is not submitted
	Decision: Deferred for submission of following: • **Evidence of availability of bilayer compression tablet facility and latest GMP inspection report conducted within last three years** • **Differential Fee of Rs. 22,500/- for pre-approval correction/change in product composition (correction/change of formulation) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
912.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Lesart 10/80mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan……..80mg Amlodipine as Besylate……..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11215 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA (40/5mg, 40/10mg, 80/5mg, 80/10mg) Tablets USFDA Approved
	Me-too-status	Cresar AM Tablet 10mg/80mg by M/s Tabros Pharma (Reg#094853)

	GMP Status	
	Previous Remark of the Evaluator [XI]	• You have applied for film coated tablets while the reference formulation is bilayered tablets. Revise your label claim, formulation and manufacturing outline as per reference formulation along with submission of applicable fee. • Provide evidence of availability of bilayered compression tablet facility • Submit latest GMP inspection report conducted within last three years
	Previous Decision (DRB-322)	• Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.
	Response of the firm	• The firm has revised the label claim, formulation and manufacturing outline as per reference formulation along with submission of Rs. 7500/- on deposit slip No#203733941574. The revised label claim is as under: Each Bilayered Tablet Contains: Telmisartan……80mg Amlodipine as Besylate……10mg • Evidence of availability of bilayered compression tablet facility and latest GMP inspection report conducted within last three years is not submitted
	Decision: Deferred for submission of following: • **Evidence of availability of bilayered compression tablet facility and latest GMP inspection report conducted within last three years** • **Differential Fee of Rs. 22,500/- for pre-approval correction/change in product composition (correction/change of formulation) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
913.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Lesart 5/40mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan……40mg Amlodipine as Besylate…….5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11212 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA (40/5mg, 40/10mg, 80/5mg, 80/10mg) Tablets USFDA Approved
	Me-too-status	Cresar AM Tablet 5mg/40mg by M/s Tabros Pharma (Reg#094850)
	GMP Status	
	Previous Remark of the Evaluator [XI]	• You have applied for film coated tablets while the reference formulation is bilayered tablets. Revise your label claim, formulation and manufacturing outline as per reference formulation along with submission of applicable fee. • Provide evidence of availability of bilayered compression tablet facility • Submit latest GMP inspection report conducted within last three years
	Previous Decision (DRB-322)	• Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.
	Response of the firm	• The firm has revised the label claim, formulation and manufacturing outline as per reference formulation along

		with submission of Rs. 7500/- on deposit slip No#65397546. The revised label claim is as under: Each Bilayered Tablet Contains: Telmisartan……40mg Amlodipine as Besylate……5mg • Evidence of availability of bilayered compression tablet facility and latest GMP inspection report conducted within last three years is not submitted
	Decision: Deferred for submission of following: • **Evidence of availability of bilayer compression tablet facility and latest GMP inspection report conducted within last three years** • **Differential Fee of Rs. 22,500/- for pre-approval correction/change in product composition (correction/change of formulation) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
914.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd., 43-E, Sundar Industrial Estate, Lahore
	Brand Name + Dosage Form and Strength	Lesart 5/80mg Tablet
	Composition	Each Film Coated Tablet Contains: Telmisartan……...80mg Amlodipine as Besylate…..…..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 11214 dated 05-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TWYNSTA (40/5mg, 40/10mg, 80/5mg, 80/10mg) Tablets USFDA Approved
	Me-too-status	Cresar AM Tablet 5mg/80mg by M/s Tabros Pharma (Reg#094852)
	GMP Status	
	Previous Remark of the Evaluator [XI]	• You have applied for film coated tablets while the reference formulation is bilayered tablets. Revise your label claim, formulation and manufacturing outline as per reference formulation along with submission of applicable fee. • Provide evidence of availability of bilayered compression tablet facility • Submit latest GMP inspection report conducted within last three years
	Previous Decision (DRB-322)	• Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.
	Response of the firm	• The firm has revised the label claim, formulation and manufacturing outline as per reference formulation along with submission of Rs. 7500/- on deposit slip No#0367675672. The revised label claim is as under: Each Bilayered Tablet Contains: Telmisartan……80mg Amlodipine as Besylate……5mg • Evidence of availability of bilayered compression tablet facility and latest GMP inspection report conducted within last three years is not submitted
	Decision: Deferred for submission of following: • **Evidence of availability of bilayer compression tablet facility and latest GMP inspection report conducted within last three years** • **Differential Fee of Rs. 22,500/- for pre-approval correction/change in product composition (correction/change of formulation) as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

Case No. 07; Deferred Registration Application of Human Drugs on form 5F (cases of Dr. Akbar Ali): Priority applications as per 257th meeting of RB

915.	Name, address of Applicant / Importer	M/s BF Biosciences Ltd 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan, Pakistan
	Details of Drug Sale License of importer	License No:05-352-0066-034461D Address: 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan. Address of Godown: NA Validity: 29-06-2027. Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	Bioprofarma Bagó S.A. Terrada 1270 - Autonomous City of Buenos Aires, Argentine Republic.
	Name, address of manufacturer(s)	Laboratorio Kemex S.A. Nazarre 3446/54 - Autonomous City of Buenos Aires, Argentine Republic.
	Name of exporting country	Argentine Republic
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. IF-2022-09064835-APN-DFYGR#ANMAT) dated 04-01-2022 issued by National Institute of Drugs Avenida Caseros 2161 Ciudad Autonoma de Buenos Aires-Republica Argentina for Fulvestrant injection 250mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Bioprofarma Bagó S.A. The letter species that the manufacturer appoints M/s BF Biosciences Ltd. to register their products in Pakistan. The authorization letter is valid till 31-01-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.31009 dated No 01-11-2022
	Details of fee submitted	PKR 75,000/-:slip No. 04893286804 dated 25-04-2022
	The proposed proprietary name / brand name	DIMERE injection 250mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Fulvestrant ……..….250mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	oestrogen receptor antagonists (L02BA03)
	Reference to Finished product specifications	In house
	Proposed Pack size	2’s

	Proposed unit price	Rs 45,000 /- single dose vial
	The status in reference regulatory authorities	FASLODEX 250mg Injection (AstraZeneca UK Limited). (Pre Filled Syringe of 5 ml)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Farmabios S.p.A. Via Pavia, 1 27027 Gropello Cairoli, (PV) – Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, 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 5oC ± 3oC. 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	Submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP type-I glass
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25 °C ± 2ºC/ 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5 °C ± 3ºC. The real time stability study data of 3 batches is for 24 months

Evaluation by PEC:

Sr. No	Observations
01	DSL of Importer /applicant is expired till 29-06-2022.
02	Provided copy of GMP certificate of API/Drug substance manufacturer, I-e M/s Farmabiosa S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 20-09-2019 was valid for 30 months, which has been expired.
03	Justification of applied container closer system of finished drug product as glass vial whereas the innovator product Faslodox is prefilled syringe.
04	Justification of overage of 0.4 ml excess filling in vial during filling process in line with innovator product which is prefilled syringe.

Previous Decision (M-324DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of firm:

Sr#	Observations	Response of Firm
01	DSL of Importer /applicant is expired till 29-06-2022.	Firm has submitted valid copy of DSL. Details of DSL are; License No:05-352-0066-034461D Address: 5-KM Sunder Raiwind Road, Raiwind, District Lahore – Pakistan. Address of Godown: NA Validity: 29-06-2027. Status: License to sell drugs as distributor Renewal: NA
02	Provided copy of GMP certificate of API/Drug substance manufacturer, I-e M/s Farmabiosa S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 20-09-2019 was valid for 30 months, which has been expired.	Firm has submitted valid copy of GMP certificate of API/Drug substance manufacturer, i.e. M/s Farmabios S.P.A Italy, issued by AIFA, Italy vide certificate No. IT-API/167/H/2020 based on inspection conducted on 2020-06-12 was valid for three years from date of inspection.
03	Justification of applied container closer system of finished drug product as glass vial whereas the innovator product Faslodox is prefilled syringe.	Dimere 250mg solution for injection is a generic drug product whose formulation, strength, pharmaceutical form and dosage form are the same as innovator product Falsodex 250mg (Lab. Astra Zeneca) Dimere container closure system differs from Faslodex finished product which is a pre-filled syringe. It consists of vials appropriately closed with stoppers and flip-off aluminium seals evidencing the same quality on materials as pre-filled syringe. Stability studies performed on Dimere dosage form confirms compatibility and that the finished product keeps the original attributes without alteration. Selecting the right primary container presentation for a product is important decision. Dimere is packed in glass vials despite pre-filled syringes advantages due to cost / benefit analysis and unavailability to access to required technology facilities to use that container.
04	Justification of overage of 0.4 ml excess filling in vial during filling process in line with innovator product which is prefilled syringe.	The firm submitted explanation as: 0.4ml (0.8%) in excess is added per vial during the filling process to ensure the deliverable volume and administration of the labelled doses. The final volume overage was empirically decided during pilot batches evaluation and compliance is confirmed batch to batch by analysis extractable volume

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 in glass vial

916.	Name, address of Applicant / Importer	M/s Martin Dow Limited., Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan.
	Details of Drug Sale License of importer	License No: 565 Address: Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: (a) 1st floor, Plot no. 211, Sector 23 Korangi Industrial Area, Karachi (b) Plot No 32, Sector 16, Korangi Industrial Area, Karachi Validity: 16-06-2024 Status: License to sell Drugs by way of Wholesale Renewal: Yes

	Name and address of marketing authorization holder (abroad)	EXELTIS HEALTHCARE, S.L. Av. Miralcampo 7 19200 Azuqueca de Henares (Guadalajara) España/Spain
	Name, address of manufacturer(s)	LABORATORIOS FARMALAN S.A. C/ La Vallina s/n, Edificio 2, Poligono Industrial Navatejera 24193 Villaquilambre (Leon) España/Spain
	Name of exporting country	Spain
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of COPP certificate (No. 2022/02191) dated 10-07-2020 issued by AGENCIA ESPAÑOLA DEL MEDICAMENTO Y PRODUCTOS SANITARIOS, Spain. Firm has submitted second original, legalized copy of CoPP certificate (No. 5.8.1-2022-64806) dated 22-08-2022 issued by Swedish Medical Products Agency. The CoPP confirms free sale status of the product in Sweden with different marketing authorization holder. The name of importing country on CoPPs is mentioned as Pakistan.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Chemo SA, Lugano branch. The letter specifies that Chemo SA, Lugano branch appoints M/s. Martin Dow Limited to register their products in Pakistan. The authorization letter is valid. Firm has also submitted a letter clarifying that Chemo has been entitled by the manufacturer and license holder to promote and distribute their product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 31354 : 02-11-2022
	Details of fee submitted	PKR 150,000/-: 31-12-2021 ,Slip No.43533251754
	The proposed proprietary name / brand name	Vestant Solution for Injection in pre-filled syringe 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Fulvestrant……50mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Anti-estrogens (ATC code: L02BA03)
	Reference to Finished product specifications	As per innovator

	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	FASLODEX Injection of ASTRAZENECA (USFDA Approved).
	For generic drugs (me-too status)	Not available
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Industriale Chimica s.r.l. Address: Via E. H. Grieg 13, 21047 Saronno (Varese), Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, 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 5oC ± 3oC and accelerated at 25°C ± 2°C. The real time stability study data is till 5 years.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established with reference product FASLODEX Pre filled syringe 250mg/5ml by establishing comparative study of critical quality attributes.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Syringe 5mL Glass Type – I and Plunger Stopper
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25oC ±2oC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5oC ±3oC. The real time stability study data of 3 batches is for 36 months.

Remarks of Evaluator:

Sr. No	Observations
01	COPP section 1.4 mentioned that this product is not actually on the market in the exporting country ,i-e Spain, please clarify.

02	Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant, is required.
03	GMP certificate of API /Drug Substance manufacturer was granted by AIFA based on GMP inspection dated 21-09-2018 valid for 3 years, which is expired, valid copy is required please.

Previous Decision (M-324-DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response against letter No. F.1-1/2020/PEC-DRAP(DD PE&R/PEC):

Sr#	Observations	Response of firm
01	COPP section 1.4 mentioned that this product is not actually on the market in the exporting country, i.e. Spain, please clarify.	The product from this same manufacturer is marketed in Sweden, for which a copy of COPP from Swedish Medical Products Agency, Box 26, Dag Hammarskjolds vag 42, 751 03 Uppsala, Sweden for Pakistan has been submitted in the dossier.
02	Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant, is required.	Sole agency agreement between the distributor i.e., Chemo SA, Lugano branch and applicant i.e., Martin Dow Limited has been submitted along with a clarification letter that Chemo SA, Lugano Branch (Distributor), Exeltis (MA Holder) and Laboratorio Farmalan (manufacturer) belong to one Insudpharma group.
03	GMP certificate of API /Drug Substance manufacturer was granted by AIFA based on GMP inspection dated 21-09-2018 valid for 3 years, which is expired, valid copy is required please.	Firm has submitted valid copy of GMP certificate of API/Drug substance manufacturer, i.e. Industriale Chimica s.r.l. Address: Via Edvard Hangerup Grieg 13, 21047 Saronno, Italy vide certificate No. NBF /2/2022/V based on inspection conducted on 2020-12-15 was valid for three years from date of inspection.
04	Finished Product analytical method validation report conducted by Finished Product manufacturer is required.	The methods of analysis of Fulvestrant 250 mg / 5 mL Solution for Injection prefilled syringe has been validated by Ricon Pharma and then transferred to Laboratorios Farmalan. Validation transfer reports of the analytical methods used for the control of Fulvestrant 250 mg / 5 mL Solution for Injection prefilled syringe are submitted
05	Stability study data revealed that batch no. 180002 at Accelerated condition of 25 degree Celsius with 60% relative humidity have significant deviation of Assay results more than 5%. Moreover, the same batch at real time stability study at 5 degree Celsius also revealed significant change in Assay results more than 5%. Please clarify.	No clarification is submitted

Decision: Deferred for submission of following:

- **Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant**
- **Finished Product analytical method validation report conducted by Finished Product manufacturer**
- **Clarification as stability study data revealed that batch no. 180002 at Accelerated condition of 25ºC with 60% relative humidity have significant change of Assay results i.e., more than 5%.**

917.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd., Address: 16km Multan Road, Lahore-Pakistan Contact details: Tel: +92 42 37511861-65 Fax: (042) 37511396-37510498 Email: info@pharmedic.com
	Name, address of Manufacturing site.	Name: Shrooq Pharmaceuticals (Pvt.) Ltd. Address: 21-km Ferozpur Road, Lahore-Pakistan. Contact details: Tel: +92-42-35274026-30
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1361 dated 16/01/2023
	Details of fee submitted	PKR 75,000/-: dated 26/01/2023 slip No .705919199860
	The proposed proprietary name / brand name	Onset Oral Solution 4mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ondansetron hydrochloride Dihydrate equivalent to Ondansetron……4mg
	Pharmaceutical form of applied drug	Clear transparent solution
	Pharmacotherapeutic Group of (API)	Antiemetic and antinauseants. Serotonin (5HT3) antagonist
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	25ml,50ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution HPRA Ireland MHRA/EMA UK
	For generic drugs (me-too status)	Onseron Oral Solution by Indus Pharma (Pvt.) Ltd. Lahore
	GMP status of the Finished product manufacturer	Last GMP was granted on 10/02/2022
	Name and address of API manufacturer.	Name: M/s. ANUGRAHA CHEMICALS Address: No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru Rural District-561203. Tel: +919845939733 / +91-8277389023 Fax : 080-28563081 E-Mail: info@anugrahachemicals.in
	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 Ondansetron as hydrochloride Dihydrate is present in (USP). The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (060, 061, 062)
	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 Onseron Oral Solution by Indus Pharma (Pvt.) Ltd. Lahore. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate),.

STABILITY STUDY DATA

Manufacturer of API	M/s. ANUGRAHA CHEMICALS		
API Lot No.	AOND-21015		
Description of Pack (Container closure system)	25ml& 50ml		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 36 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 (Months)		
Batch No.	060	061	062
Batch Size	1000 L	1000 L	1000 L
Manufacturing Date	05.2022	06.2022	07.2022
Date of Initiation	05.2022	06.2022	07.2022
No. of Batches	03		

Administrative Portion

1	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No: DCD/SPL-1/CR-1733/2021/02 Valid up to 30.01.2023 Issued BY: Govt. of Karnataka, Drug Control Department, India DML License No: KTK/25/549/2008 Valid up to: 13/02/2025 Issued BY: Govt. of Karnataka, Drug Control Department, India
3	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

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

Remarks of Evaluator:

Sr#	Section	Observations
01	3.2.S.3.1	The Molecular weight of Drug substance (Ondansetron Hcl dehydrate) is mentioned as 329.82 g/mol whereas USP has mentioned molecular weight as 365.85. Clarification is required.
02	3.2.S.4	Drug substance analytical method verification studied conducted by drug substance manufacturer and Finished product manufacturer are missing, which are required. Provided copy of COA of Drug Substance Batch No AOND-21015 mentioned Ondansetron Hcl (Tablet grade) .please clarify.
03	3.2.P.1	Finished manufacturer has mentioned Glycerin and poly sucralose as excipients in their formulation which are not present in Reference product, Syp Zofran 4gm/5ml approved by MHRA. Please clarify.
04	3.2.P.8.3	Stability study data of 3 batches for real time and accelerated conditions for 6-month time point is missing which is required. Documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision (M-324-DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of Firm:

Sr#	Observations	Response of firm
01	The Molecular weight of Drug substance (Ondansetron Hcl dehydrate) is mentioned as 329.82 g/mol whereas USP has mentioned molecular weight as 365.85. Clarification is required.	Molecular weight of substance has been corrected as 365.85 g/mol.
02	• Drug substance analytical method verification studied conducted by drug substance manufacturer and Finished product manufacturer are missing, which are required. • Provided copy of COA of Drug Substance Batch No AOND-21015 mentioned Ondansetron Hcl (Tablet grade) please clarify.	• Analytical method verification studies for drug substance by finished product manufacturer have been submitted. • Drug substance manufacturer is manufacturing API for injection as well. That's why uses this identification. COA with revised identification as Ondansetron HCl has been provided. The firm further submitted declaration from drug substance manufacturer that same API can be used to product both Tablets and Syrup
03	Finished manufacturer has mentioned Glycerin and poly sucralose as excipients in their formulation which are not present in Reference product, Syp Zofran 4gm/5ml approved by MHRA. Please clarify.	The firm has submitted evidence of ondansetron hydrochloride solution by M/s Chartwell RX, LLC wherein Glycerin and sucrose has been used along with other excipients. Justification for poly sucralose is not submitted
04	• Stability study data of 3 batches for real time and accelerated conditions for 6-month time point is missing which is required. • Documents for the procurement of API with approval from DRAP (in case of import).	• Stability study for the 6th month time point has been submitted. • Firm has submitted copy of invoice No. EXP-35 dated 17-12-2021 for import of 20Kg of Ondansetron Hydrochloride USP

		Tablet grade (Batch No# AOND-21015) in name of M/s Sharooq Pharmaceutical Pvt. Ltd., attested by AD (I&E) DRAP Lahore dated 23-12-2021.

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.**

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Compatibility studies of the Drug Substance with excipients**
- **Pharmaceutical equivalence and CDP studies against the innovator product.**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km Ferozpur Road, Lahore.

Case No. 08; Deferred Registration Application of Human Drugs on form 5F (cases of Dr. Akbar Ali): (Export Facilitation)

918.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.13727 dated 07/06/2022
	Details of fee submitted	PKR 75,000/-: dated 20/05/2022 (Slip No.6973977486)
	The proposed proprietary name / brand name	Acotide 100mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Acotiamide HCl hydrate…….100mg
	Pharmaceutical form of applied drug	Blue in color, biconvex, round shaped, film coated tablet, engraved SEARLE on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Gastroprokinetic
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by PMDA (JAPAN) and marketed in JAPAN, with the name of Acofide Tablets 100mg
	For generic drugs (me-too status)	N.A
	GMP status of the Finished product manufacturer	New license granted on 13/08/2020 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**Manufacturer:.** Emmennar Pharma Private Limited

		Address: Plot No. A-4, Industrial Estate, Opposite Sanath Nagar Police Station, Sanath Nagar, Hyderabad, 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, 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 Paroxetine Hydrochloride 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 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 / 75% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ACT2-1704002, ACT2-1704003, ACT2-1704004)
	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 Acofide 100mg tablet, PMDA (Japan) approved by Zeria Pharmaceutical.Co., Ltd by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Acofide 100mg tablet, PMDA (Japan) approved by Zeria Pharmaceutical.Co., Ltd in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Manufacturer:** Emmennar Pharma Private Limited **Address:** Plot No. A-4, Industrial Estate, Opposite Sanath Nagar Police Station, Sanath Nagar, Hyderabad, Telangana, India
API Lot No.	ACT2M-20004

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21PD-024	21PD-025	21PD-026
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Feb-2021	Feb-2021	Feb-2021
Date of Initiation	March-2021	March-2021	March-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP Certificate** Manufacturer: Emmennar Pharma Private Limited. Valid Till: 04-02-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Form 3:** Form of Undertaking to Accompany an Applicant for License to Import Drugs **Form 6:** License to import Raw material for manufacturing Trial Examination, test or Analysis **Form 7:** Batch Certification **Invoice** Invoice Num: 210018 Quantity: 1.5 kgs Batch: ACT2M-20004 Mfg Date: Feb-2020 Exp Date: Jan-2024 **Packing List** Invoice Num: 210018 Quantity: 1.5 kgs Batch: ACT2M-20004 Mfg Date: Feb-2020 Exp Date: Jan-2024 **COA of API** from drug substance and Drug product Manufacturer **Testing Method of API** from drug substance and Drug product Manufacturer **Stability Data** of API from API manufacturer
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr#	Section	Observations
01	2.3.S.3.1.2	API manufacturer has mentioned that "Acotiamide Hcl Hydrate exhibits polymorphism". However, the data of Innovator product registered with PDMA mentions that" The drug substance is a trihydrate and has a single crystal form. No crystalline polymorphism is observed." Please clarify .

02	3.2.S.4.2	Substance manufacturer has mentioned Identification testing of Acotiamide Hcl hydrate through Infrared Absorption spectroscopy following USP 197 K by using Kbr pellets, however the drug substance testing specifications provided by finished product manufacturer in 3.2.S.4.4.1 mentioned Identification through FTIR. Clarification is required.
03	3.2.S.4	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted. Please provide.
04	2.3.P.5.1	HPLC Retention time of Acotiamide Hcl hydrate mentioned by substance manufacturer is 11.83 whereas on same chromatographic conditions the retention time of Acotiamide Hcl hydrate in Drug product is mentioned as 8.3 minutes, please clarify. HPLC Run time of sample in drug substance assay testing specification is different from drug product run time , Clarification is required.
05	3.2.P.8	Legible/readable copy of DRAP attested copy if import invoice of API from source is required.

Previous Decision (DRB-324): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of firm:

Sr#	Observations	Response of firm
01	API manufacturer has mentioned that "Acotiamide Hcl Hydrate exhibits polymorphism". However, the data of Innovator product registered with PDMA mentions that" The drug substance is a trihydrate and has a single crystal form. No crystalline polymorphism is observed." Please clarify .	The firm submitted that upon query, API manufacturer admit that it was a typographical error; and only one crystal form of Acotiamide Hydrochloride exists. The XRD data and other relevant documents also assure that the Manufacturer's Acotiamide Hydrochloride Trihydrate is same as the innovator. Furthermore, manufacturer also correct the mistake and shared the revised DMF.
02	Substance manufacturer has mentioned Identification testing of Acotiamide Hcl hydrate through Infrared Absorption spectroscopy following USP 197 K by using Kbr pellets, however the drug substance testing specifications provided by finished product manufacturer in 3.2.S.4.4.1 mentioned Identification through FTIR. Clarification is required.	The firm submitted that we, The Searle Company Limited followed the USP general monograph having title " <197> Spectroscopic Identification Test" for identification via IR spectrophotometer which suggest Seven methods for analysis by infrared spectroscopy in which each of the method can be used as alternative method and we adopted <197A> test for identification which is the latest identification technique.
03	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. Please provide.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision), linearity, range, system suitability performed by the Drug Product manufacturer for drug substance is submitted.
04	HPLC Retention time of Acotiamide Hcl hydrate mentioned by substance manufacturer is 11.83 whereas on same chromatographic conditions the retention time of Acotiamide Hcl hydrate in Drug product is mentioned as 8.3 minutes, please clarify. HPLC Run time of sample in drug substance assay testing specification is different from drug product run time , Clarification is required.	The firm submitted that we, The Searle Company Limited took the drug substance manufacture method i.e. Mobile Phase A, Mobile Phase B, Diluent, Chromatographic condition, for assay analysis of drug product in which further optimization of Gradient elution has been done by converting in to Isocratic elution to enhance accuracy and precision, improved (Shortened) run time which reduce the testing time and resources. Furthermore the method has been validated and the same has been submitted that is why run time of drug product is differ from drug substance method.
05	Legible/readable copy of DRAP attested copy if import invoice of API from source is required.	Firm has submitted copy of invoice No. 210018 dated 07-10-2020 for import of 1.5kg of Acotiamide Hydrochloride Hydrate (Batch No# ACT2M-20004) in name of The Searle Company

	Limited attested by AD (I&E) DRAP Karachi dated 22-10-2020. Firm has also submitted copy of form 6 dated 22-10-2020 for import of 1.5kg of Acotiamide Hydrochloride Hydrate in name of The Searle Company Limited attested by AD (I&E) DRAP Karachi dated 22-10-2020.
Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7,500/- for correction/pre-approval changes in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

Agenda of Evaluator PEC-XIII.

Case 01; Registration applications of New DML/New section (Human) drugs on Form 5F.

919.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30369; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 3603520460 dated 27/09/2022.
	The proposed proprietary name / brand name	Sinocef 125mg Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cephradine ……..…… 125mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	First generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 60ml and 1 x 90ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Suprax 100mg /5ml Dry Suspension by M/s Lupin Pharma, USFDA Approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Caricef 100mg /5ml Dry Suspension, M/s Sami Pharmaceuticals, Reg. No. 022415.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and

		Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore. Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	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, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis (B. No. 00243/081/22 date of analysis 12-05-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 03 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 b months. Batches: (00244/135/2010, 00244/136/2010 & 00244/137/2010)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the brand Caricef 100mg/5ml Dry Suspension, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.
API Lot No.	00243/081/2022
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 60ml.
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-007	TR-008	TR-009
Batch Size	275 Bottle	275 Bottle	275 Bottle
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not 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 number	Observation	Response by the firm.
1.	1.5.9	Provide evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board in its 275th meeting for further processing of your case as the submitted reference of USFDA is discontinued"	

Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

920.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 30367; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 8595581239 dated 27/09/2022.
	The proposed proprietary name / brand name	Sinocef 250mg Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cephradine …….…… 250mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	First generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 60ml and 1 x 90ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml / Cefradine Syrup 250mg/5ml MHRA approved. Active Ingredient Per 5ml Cefradine 250 mg
	For generic drugs (me-too status)	Velosef 250mg Suspension, GSK Pakistan, Reg. No. 001868.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore. Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	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 Cephradine is available in USP & BP. Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis (B. No. 00203/038/2022, mfg. date 03-2022) 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. Stability study conditions: Real time: 5˚C ± 3˚C %RH for 36 months Accelerated: 25˚C ± 2˚C / 60% ± 5%RH for 6 months Batch No. (00202/001/2008, 00202/050/2008 & 00202/100/2008)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the cephradine suspension 250mg/5ml, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 90ml.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-004	TR-005	TR-006
Batch Size	263 Bottle	263 Bottle	263 Bottle
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	25-06-2022	25-06-2022	25-06-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not 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 number	Observation	Response by the firm.
1.	1.5.2	Justification shall be submitted regarding the label claim of the applied formulation as the label claim has only cephradine while the executed BMR's, Batch formula and COA for the finished product has Cephradine as monohydrate.	
2.	3.2.S.4.1	• Specification for the drug substance by the drug product manufacturer shall be submitted. • Firm has submitted BP and USP specifications for the drug substance wherein no limits for 4,5 dihydrocefradine are given while BP has mentioned the same. Clarify.	
3.	3.2.S.4.2	• Analytical procedures for the drug substance by the drug product manufacturer shall be submitted. • Concentration of the standard and test samples in analytical procedures from the drug substance manufacturer are different from BP. Justification shall be submitted.	
4.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	
5.	3.2.S.4.4	• Justify the physical form of the drug substance whether monohydrate or otherwise. • COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted. • COA submitted by the drug substance manufacturer has mentioned that it complies with BP specifications while submitted COA have no limits for 4,5 dihydrocepfradine and BP has mentioned it. Justify.	
6.	3.2.S.5.	• Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarification shall be submitted. • Working standard standardized against the reference standard has mentioned that use before 26, October 2016. Clarify.	
7.	3.2.P.1	Qualitative composition of the applied formulation is different from reference product. Justification shall be submitted.	
8.	3.2.P.2	• Justification for not performing Pharmaceutical Equivalence against the innovator brand shall be submitted. • In one page PE against Sami pharma product is established while on another page PE against Velosef suspension by GSK pharma is submitted. Calrify. • Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method.	

		• No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	
9.	3.2.P.5.1	Specification provided for drug product by the drug product manufacturer has different pH limits from pharmacopoeia and also not mentioned cephalexin in assay test.	
10.	3.2.P.5.4	COA for the finished product has only mentioned cephradine while the USP has mentioned sum of Cephradine and cephalexin. Clarification shall be submitted.	•
11.	3.2.P.5.3	• Method verification protocol shall be submitted. • Sample and standard solution preparation used in method verification studies shall be submitted. • Provide justification for accuracy range i.e 90% - 110%.	•
12.	3.2.P.8	• Justify the label claim of the applied formulation in the assay calculation of submitted chromatograms as 25mg is claimed while the actual value is 50mg. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • API lot number used during the development studies shall be mentioned in the stability data sheets. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

921.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30370; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 2161416456 dated 27/09/2022.

	The proposed proprietary name / brand name	S- Xime 100mg/ 5ml Dry Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime as trihydrate …….…… 100mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 30ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Suprax 100mg /5ml Dry Suspension by M/s Lupin Pharma, USFDA Approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Caricef 100mg /5ml Dry Suspension, M/s Sami Pharmaceuticals, Reg. No. 022415.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore. Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	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, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis (B. No. 00243/081/22 date of analysis 12-05-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 03 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 b months. Batches: (00244/135/2010, 00244/136/2010 & 00244/137/2010)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the brand Caricef 100mg/5ml Dry Suspension, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.		
API Lot No.	00243/081/2022		
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 60ml.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-007	TR-008	TR-009
Batch Size	275 Bottle	275 Bottle	275 Bottle
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not 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 number	Observation	Response by the firm.
1.	3.2.S.4.1	Specification for the drug substance by the drug product manufacturer shall be submitted.	
2.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	
3.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.4	COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted.	
5.	3.2.S.7.3	Justification shall be submitted for performing only few tests in the stability studies of drug substance.	
6.	3.2.P.2	pH of the product mentioned in pharmaceutical development is 2.6 – 4.1 while official pharmacopoeia has mentioned 2.5 – 4.5. justify.	
7.	3.2.P.2	• Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method. • No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	
8.	3.2.P.3.2.	Batch formula has mentioned Cefixime trihydrate 100 instead of Cefixime as trihydrate 100. Revised batch formula along with applicable fee shall be submitted.	•
9.	3.2.P.5.3	• Method verification protocol shall be submitted. • Sample and standard solution preparation used in method verification studies shall be submitted. • Provide justification for accuracy range i.e 90% - 110%.	•
10.	3.2.P.8	• Official pharmacopoeia has mentioned that Adjust flow rate so that the retention time of Cefixime is about 10 min while all the submitted chromatograms has run time of 6 to 7 minutes and retention time is about 3 minutes. • Submitted chromatograms does not reveal system suitability parameters as required by the USP monograph. Justify. • Submitted chromatograms does not column efficiency as required by the USP monograph. Justify. • API lot number is not mentioned in stability data sheets. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.		
922.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30368; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 467147674916 dated 27/09/2022.
	The proposed proprietary name / brand name	S- Xime 200mg/ 5ml Dry Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime as trihydrate ……..…… 200mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 30ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Suprax 200mg /5ml Dry Suspension by M/s Lupin Pharma, USFDA Approved.
	For generic drugs (me-too status)	Caricef DS 200mg /5ml Dry Suspension, M/s Sami Pharmaceuticals, Reg. No. 044340.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.

		Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis (B. No. 00243/081/22 date of analysis 12-05-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 03 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 b months. Batches: (00244/135/2010, 00244/136/2010 & 00244/137/2010)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the brand Caricef 200mg/5ml Dry Suspension, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.		
API Lot No.	00243/081/2022		
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 60ml.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-010	TR-011	TR-012
Batch Size	275 Bottle	275 Bottle	275 Bottle
Manufacturing Date	06-2022	06-2022	06-2022

Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not 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 number	Observation	Response by the firm.
1.	3.2.S.4.1	Specification for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted verification studies of the drug substance including specificity, accuracy and precision. Linearity and range are not verified.
4.	3.2.S.4.4	COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted.	COAs of the drug substance from both drug substance manufacturer and finished product manufacturer are submitted.
5.	3.2.S.7.3	Justification shall be submitted for performing only few tests in the stability studies of drug substance.	Firm has submitted that stability studies are conducted on stability specifications which are different from the release or shelf life specifications. Usually those tests are performed in stability studies which are expected to be affected by temperature and humidity conditions over the period of time. Pharmagen is a DRAP approved API manufacturer and its stability study data for Cefixime has been accepted by Registration Board in various meetings.
6.	3.2.P.2	• Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method.	Firm has submitted that they perform pharmaceutical equivalence studies using the same method provided in 3.2.P.5.1 & 3.2.P.5.2 and there was some typographical mistake while compiling dossier and by mistake some UV method was attached. *Submitted raw data in the originally submitted dossier is from UV method and no data of HPLC is submitted by the firm.*

		• No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	Firm has submitted details of the innovator product as follows; Batch No. D1836, Mfg. date 06-2022, Exp. Date 05, 2024
7.	3.2.P.3.2.	Batch formula has mentioned Cefixime trihydrate 100 instead of Cefixime as trihydrate 100. Revised batch formula along with applicable fee shall be submitted.	Firm has submitted revised batch formula for the applied formulation without submission of applicable fee.
8.	3.2.P.5.3	• Method verification protocol shall be submitted.	**Not submitted.**
		• Sample and standard solution preparation used in method verification studies shall be submitted.	Firm has submitted that sample and standard preparation method used in verification studies are exactly same as defined in the analytical procedures of drug product. However, dilution prepared for the verification studies are not provided.
		• Provide justification for accuracy range i.e 90% - 110%.	Firm has submitted that accuracy range was mistakenly written as 90% - 110%, now we have corrected the range and our results were within the limit of ±2% as defined by ICH guidelines.
9.	3.2.P.8	• Official pharmacopoeia has mentioned that Adjust flow rate so that the retention time of Cefixime is about 10 min while all the submitted chromatograms has run time of 6 to 7 minutes and retention time is about 3 minutes.	Firm has submitted that they have performed verification studies and system suitability studies as defined by USP. During verifications studies they have performed HPLC analysis for run time greater than 10 minutes, but our analyte peak was observed from 3 to 4 minutes so as per USP recommendations they adjusted the HPLC run time to 07 minutes. Both standard as well as sample analysis show similar retention time which justify the identification as well as other analytical tests. Conditions applied are similar to USP however, retention time is not in line with USP.
		• Submitted chromatograms does not reveal system suitability parameters as required by the USP monograph. Justify.	Firm has submitted that their default software for HPLC show limited options while printing HPLC chromatograms however, all parameters related to system suitability like number of theoretical plates, tailing factor, column efficiency etc. are recorded and saved within the system for each chromatograms.
		• Submitted chromatograms does not column efficiency as required by the USP monograph. Justify.	
		• API lot number is not mentioned in stability data sheets.	Firm has stated that API lot number is 00243/081/22. ***However, the Purchase invoice has some other batch number of the raw material.*** Firm has submitted copy of invoice No. 2645 dated 10-05-2022 mentioning Cefixime micronized with batch No. 00243-04/081/2022 with 2kg quantity.
		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted that their HPLC system is not 21 CFR compliant however they have maintained all relevant logs as per the GMP requirements. Submitted.
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	
		• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted that they have recently been granted with manufacturing license and till date they have not received any approval of application with stability data. Submitted.

	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	
Decision: Deferred for the following; • **Performance of Assay test in Pharmaceutical equivalence studies, as per USP monograph.** • **Justification shall be submitted for retention time of Cefixime with respect to the USP which states that "Adjust flow rate so that the retention time of Cefixime is about 10 min" while all the submitted chromatograms has "run time" of 6 to 7 minutes and retention time is about 3 minutes.** • **Justification shall be submitted for difference in the API lot number in stability summary data sheets and purchase invoice.** • **Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**		
CLB in its 284th meeting held on 16th December 2021 has considered and approved the grant of following four (04) additional section to M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura; • Capsule (Penicillin). – New. • Oral Dry Powder Suspension (Penicillin). – New. • Dry Powder Injectable (Penicillin). – New. • Dry Powder Injectable (Carbapenem). – New. Following applications of M/s Fynk Pharma are placed before the Board for consideration.		
923.	Name, address of Applicant / Marketing Authorization Holder	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, 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. 477 dated 05-01-2023.
	Details of fee submitted	PKR 30,000/-, vide slip No. 3316253310, Dated 12/12/2022.
	The proposed proprietary name / brand name	**FAXCIL 125 mg/5ml suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as Trihydrate ……..……. 125 mg.
	Pharmaceutical form of applied drug	Powder for oral suspension.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	1's
	Proposed unit price	100/-
	The status in reference regulatory authorities	Amoxil-125mg/5ml, 250mg/5ml, USFDA approved. 125mg/5ml **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**

	For generic drugs (me-too status)	Amoxil 125mg/5ml dry suspension, GSK Karachi, Reg. No. 000508.
	GMP status of the Finished product manufacturer	New license for additional sections granted on 16/12/2021.
	Evidence of section approval	Oral dry powder suspension (Penicillin) section - New approved vide letter No. F. 1-63/84-Lic (Vol-III) dated 27-12-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
	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 Amoxicillin trihydrate is present in BP. The firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. 000120/841/2021, mfg. date 12-2021) 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: (00013/210/2009, 00013/211/2009, 00013/212/2009)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, 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 Amoxil 125 mg Suspension manufactured by GSK Pharma by performing quality tests (Identification, Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
API Lot No.	000120/841/2021.
Description of Pack (Container closure system)	Faxcil Suspension 125mg/5ml is packed in Amber colored Glass bottle packaging that is further packed in cardboard unit carton along with patient leaflet 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: 06 months

	Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FX-125(TR-001)	FX-125(TR-002)	FX-125(TR-003)
Batch Size	100 bottle	100 bottle	100 bottle
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	20-02-2022	20-02-2022	20-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product D-Lazol 30mg capsules which was conducted on 07-09-2021 and was presented in 312th meeting of Registration Board (14 - 16 September, 2021). Report has confirmed that HPLC used in the analysis has HPLC software that is 21 CFR compliant and compliance certificate from the vendor was available. Audit trial of the system on which testing was reviewed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Performa invoice No. PL/P-INV/HO /866 dated 03-01-2022 mentioning 5kg of the active ingredient is submitted. *However, no batch number is mentioned on the invoice.*
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection conducted on 14-11-2022.
2.	1.6.5	Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. *GMP certificate of the drug substance manufacturer is not valid.*
3.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2..4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted method verification studies of the drug substance performed by the drug product

			manufacturer including Specificity, accuracy and precision.
6.	3.2.S.5	Details and COA of the working standard used shall be submitted.	Submitted.
7.	3.2.P.1	Qualitative composition of the applied formulation is different from the reference product. Clarification shall be submitted.	*No justification is submitted by the firm.*
8.	3.2.P.2.2	No details of the reference product are provided in Pharmaceutical Equivalence.	*Still no details are provided by the firm.* *Only the name of the manufacturer is provided while Batch number, manufacturing date, expiry date and evidence of the pack used for CDP and pharmaceutical equivalence is not provided.*
9.	3.2.P.5.4	COAs of all the three trial batches shall be submitted.	Submitted.
10.	3.2.P.8	Justify the standard preparation in batch analysis record with respect to the analytical procedure.	Firm has submitted that as in analytical procedure standard preparation is 0.070% as per BP, that is equivalent to 0.70mg/ml. In batch analysis record, during bulk analysis standard was 0.50mg/ml that was approximate to sample preparation (0.60mg/ml). but from finished product to all stability testing it was 0.70mg/ml.

Decision: Deferred for the following;

- **Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.**
- **Justification shall be submitted for difference in qualitative composition of the applied formulation from Innovator product.**
- **Details of the reference product used for Pharmaceutical Equivalence studies i.e. Batch number, manufacturing date, expiry date shall be submitted.**
- **Scientific justification shall be submitted for using 0.50mg/ml standard solution in batch analysis while BP has mentioned 0.70mg/ml concentration for the standard solution.**

924.	Name, address of Applicant / Marketing Authorization Holder	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, 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. 478 dated 05-01-2023.
	Details of fee submitted	PKR 30,000/-, vide slip No. 855718472484, Dated 12/12/2022.
	The proposed proprietary name / brand name	**FAXCIL 250 mg/5ml suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Amoxicillin as Trihydrate ……..……. 250 mg.
	Pharmaceutical form of applied drug	Powder for oral suspension.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Reference to Finished product specifications	BP Specifications.
	Proposed Pack size	1's

	Proposed unit price	150/-
	The status in reference regulatory authorities	Amoxil-125mg/5ml, 250mg/5ml, USFDA approved. 125mg/5ml **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Amoxil forte 250mg/5ml dry suspension, GSK Karachi, Reg. No. 006814.
	GMP status of the Finished product manufacturer	New license for additional sections granted on 16/12/2021.
	Evidence of section approval	Oral dry powder suspension (Penicillin) section - New approved vide letter No. F. 1-63/84-Lic (Vol-III) dated 27-12-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
	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 Amoxicillin trihydrate is present in BP. The firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. 000120/841/2021, mfg. date 12-2021) 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: (00013/210/2009, 00013/211/2009, 00013/212/2009)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, 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 Amoxil 250mg/5ml Suspension manufactured by GSK Pharma by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
API Lot No.	000120/841/2021.

Description of Pack (Container closure system)	Faxcil Suspension 250mg/5ml is packed in Amber colored Glass bottle packaging that is further packed in cardboard unit carton along with patient leaflet 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: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FX-250(TR-001)	FX-250(TR-002)	FX-125(TR-003)
Batch Size	100 bottle	100 bottle	100 bottle
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	20-02-2022	20-02-2022	20-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product D-Lazol 30mg capsules which was conducted on 07-09-2021 and was presented in 312th meeting of Registration Board (14 - 16 September, 2021). Report has confirmed that HPLC used in the analysis has HPLC software that is 21 CFR compliant and compliance certificate from the vendor was available. Audit trial of the system on which testing was reviewed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Performa invoice No. PL/P-INV/HO /866 dated 03-01-2022 mentioning 5kg of the active ingredient is submitted. *However, no batch number is mentioned on the invoice.*
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection conducted on 14-11-2022.
2.	1.6.5	Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted. *GMP certificate of the drug substance manufacturer is not valid.*
3.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.	Submitted.

4.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2..4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted method verification studies of the drug substance performed by the drug product manufacturer including Specificity, accuracy and precision.
6.	3.2.S.5	Details and COA of the working standard used shall be submitted.	Submitted.
7.	3.2.P.1	Qualitative composition of the applied formulation is different from the reference product. Clarification shall be submitted.	*No justification is submitted by the firm.*
8.	3.2.P.2.2	No details of the reference product are provided in Pharmaceutical Equivalence.	*Still no details are provided by the firm.* *Only the name of the manufacturer is provided while Batch number, manufacturing date, expiry date and evidence of the pack used for CDP and pharmaceutical equivalence is not provided.*
9.	3.2.P.5.4	COAs of all the three trial batches shall be submitted.	Submitted.
10.	3.2.P.8	Justify the standard preparation in batch analysis record with respect to the analytical procedure.	Firm has submitted that as in analytical procedure standard preparation is 0.070% as per BP, that is equivalent to 0.70mg/ml. In batch analysis record, during bulk analysis standard was 0.50mg/ml that was approximate to sample preparation (0.60mg/ml). but from finished product to all stability testing it was 0.70mg/ml.

Decision: Deferred for the following;

- **Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.**
- **Justification shall be submitted for difference in qualitative composition of the applied formulation from Innovator product.**
- **Details of the reference product used for Pharmaceutical Equivalence studies i.e. Batch number, manufacturing date, expiry date shall be submitted.**
- **Scientific justification shall be submitted for using 0.50mg/ml standard solution in batch analysis while BP has mentioned 0.70mg/ml concentration for the standard solution.**

New license granted on 13/09/2021
Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.

925.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 846; dated 10-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 868427408767 dated 16/11/2022.
	The proposed proprietary name / brand name	**Gasdex 30mg Capsules.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole Dual Delayed Released Pellets (17%) Equivalent to Dexlansoprazole ……30mg

	Pharmaceutical form of applied drug	Pellet Filled HPMC Capsule, Size 2
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsules 30mg & 60mg, USFDA Approved.
	For generic drugs (me-too status)	Razodex 30mg Capsules, M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 086976.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan. Copy of GMP certificate No.F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
	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)	Firm has submitted detail of drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. DLP864, mfg. date 24-02-2022) 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 data sheets for drug substance. Stability data conditions are as follows: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months. Batch No. (DLP260, DLP252 & DLP253)
	Module-III (Drug Product):	Firm has submitted detail of the drug product regarding its description & composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, impurities, 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 Razodex 30mg Capsules, B. No.

		064C47, mfg. date 08-2021 manufactured by M/s Getz Pharma, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP is also performed against the same brand that is Razodex 30mg Capsules, B. No. 064C47, mfg. date 08-2021 manufactured by M/s Getz Pharma, in Acid media of 0.1N, Buffer (pH 5.5) and 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 (Repeatability), specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu. Alu. Blister strips of 3x10 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T062	T063	T064
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	17-06-2022	17-06-2022	17-06-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 30's as proposed pack size for the applied formulation.

2.	3.2.S.4.1	Neither drug substance manufacturer nor drug product manufacturer has mentioned that assay in on anhydrous basis or as is basis.	Firm has submitted that drug pellets manufacturer has claimed assay of drug substance on as is basis and same is from finished product manufacturer.
3.	3.2.S.4.4	COA from drug substance manufacturer potency is on anhydrous basis or as is basis.	Firm has submitted COA from the drug substance manufacturer wherein the potency is on as is basis.
4.	3.2.S.5	Details and COA of the working standard used during formulation development shall be submitted.	Submitted.
5.	3.2.S.6	Justification shall be submitted regarding packaging material used during the stability studies of the drug substance as section 3.2.S.6 has mentioned LDPE and HDPE while the stability data sheets has mentioned PET bottles.	Firm has submitted that stability samples are filled in polybags and finally packed in HDPE bottles, they also submitted corrected and updated stability data for the drug substance.
6.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Dexilant is innovator product and at the time of studies the innovator sample was not available in the local market and we performed CDP & PE against razodex 30mg capsules manufactured by Getz pharma.
		• Comparison of CDP in all the three mediums separately shall be submitted.	Firm has submitted revised CDP results for the applied formulation in acidic medium pH 1.2 and buffer pH 6.8.
7.	3.2.P.5.1	Drug product specifications has mentioned assay as BP specifications. Clarify.	Firm has submitted revised specifications for the drug product wherein they have changed BP specifications to Innovator's specifications. ***Fee required for pre-registration variation is not submitted.***
8.	3.2.P.5.2	• Analytical procedures for assay test of the finished product has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.05mg/ml strength of standard solution. Clarification shall be submitted.	Firm has submitted that it was typo error and concentration of both sample and standard preparation 0.01mg/ml. they also submitted corrected and revised testing method.
		• Similarly, sample solution has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.025mg/ml strength of sample solution. Clarification shall be submitted.	
		• Calculation formula for assay test is also different from the analytical procedure. Justify.	Firm has also submitted calculation formula.
9.	3.2.P.8	• Justify the weight of standard in assay test with respect to the analytical procedure for assay test.	Firm has submitted that this mistake was due to typo error in the testing method which has now been rectified.
		• Justify the weight of standard in dissolution test with respect to the analytical procedure for dissolution test.	Firm has submitted rectified testing method wherein the standard preparation in the dissolution test has mentioned that "take accurately weighed Dexlansoprazole working standard (on anhydrous basis) equivalent to 50mg" *However, the raw data sheets have clearly mentioned 30mg which is not justified by the firm.*
		• 92.56% potency used in assay and dissolution test shall be justified.	Firm has submitted COA of the working standard used in the trial batches and has potency of 92.56.
		• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets.	Firm has submitted revised stability data sheets with inclusion of API lot number.

	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	***Not submitted.*** ***Not submitted.*** ***Not submitted.***

Decision: Deferred for following:

- **Justification for variation in the standard solution concentration as declared n raw data sheets from that mentione din the drug oridyct analytical oricedure for Assay & Dissolution test.**
- **Justification for variation in calculation formula applied in the raw data sheet from that mentioned in the drug product analytical procedure for Assay test.**
- **Clarification for variation in the API lot# mentioned in the stability summary sheet from that declared on the drug substance COA.**
- **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**

926.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 847; dated 10-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 23808790439 dated 16/11/2022.
	The proposed proprietary name / brand name	Gasdex 60mg Capsules.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole Dual Delayed Released Pellets (22.5%) Equivalent to Dexlansoprazole ……60mg
	Pharmaceutical form of applied drug	Pellet Filled HPMC Capsule, Size 2
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsules 30mg & 60mg, USFDA Approved.
	For generic drugs (me-too status)	Razodex 60mg Capsules, M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 086977.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.

	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan. Copy of GMP certificate No.F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
	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)	Firm has submitted detail of drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. DLP865, mfg. date 24-03-2022) 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 data sheets for drug substance. Stability data conditions are as follows: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (DLP125T, DLP124T & DLP123T)
	Module-III (Drug Product):	Firm has submitted detail of the drug product regarding its description & composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, impurities, 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 Razodex 60mg Capsules, B. No. 061C48, mfg. date 08-2021 by M/s Getz Pharma, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP is also performed against the same brand that is Razodex 60mg Capsules, B. No. 061C48, mfg. date 08-2021 by M/s Getz Pharma, in Acid media of 0.1N, Buffer (pH 5.5) and 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 (Repeatability), specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.
API Lot No.	NA
Description of Pack (Container closure system)	Alu. Alu. Blister strips of 3x10 Capsules packed in unit carton.

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T065	T066	T070
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	17-06-2022	17-06-2022	17-06-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 30's as proposed pack size for the applied formulation.
2.	2.3.R	Table for literature references has mentioned USP for drug substance and drug product while there is no official monograph for dexlansoprazole pellets. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted revised table for literature references wherein they have not mentioned anything against the drug substance and drug product with submission of 7500/- fee vide slip No. 1377271048 dated 02-03-2023.
3.	3.2.S.4.1	Neither drug substance manufacturer nor drug product manufacturer has mentioned that assay in on anhydrous basis or as is basis.	Firm has submitted that drug pellets manufacturer has claimed assay of drug substance on as is basis and same is from finished product manufacturer.
4.	3.2.S.4.4	COA from drug substance manufacturer potency is on anhydrous basis or as is basis.	Firm has submitted COA from the drug substance manufacturer wherein the potency is on as is basis.
5.	3.2.S.5	Details and COA of the working standard used during formulation development shall be submitted.	Submitted.
6.	3.2.S.6	Justification shall be submitted regarding packaging material used during the stability studies of the drug substance as	Firm has submitted that stability samples are filled in polybags and finally packed in HDPE bottles, they

		section 3.2.S.6 has mentioned LDPE and HDPE while the stability data sheets has mentioned PET bottles.	also submitted corrected and updated stability data for the drug substance.
7.	3.2.S.7.3	• Specifications has mentioned release in buffer pH 5.5 of 15-40% in one hour while the stability data sheet has mentioned NMT 30%. Clarification shall be submitted. • Similarly, the release in pH 7 medium has different values than mentioned in specifications. Justify.	Firm has submitted that previously submitted stability data was of trial batches and testing performed on stringent specifications, to get confidence on formulation prior to commercialize. But from very first commercial consignment, specifications were same as mentioned in shared COA and recently provided stability data is of commercial lots and on the same specifications.
8.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted. • Comparison of CDP in all the three mediums separately shall be submitted.	Firm has submitted that Dexilant is innovator product and at the time of studies the innovator sample was not available in the local market and we performed CDP & PE against razodex 60mg capsules manufactured by Getz pharma. Firm has submitted revised CDP results for the applied formulation in acidic medium pH 1.2 and buffer pH 6.8.
9.	3.2.P.5.1	Drug product specifications has mentioned assay as BP specifications. Clarify.	Firm has submitted revised specifications for the drug product wherein they have changed BP specifications to Innovator's specifications.
10.	3.2.P.5.2	• Analytical procedures for assay test of the finished product has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.05mg/ml strength of standard solution. Clarification shall be submitted. • Similarly, sample solution has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.025mg/ml strength of sample solution. Clarification shall be submitted. • Calculation formula for assay test is also different from the analytical procedure. Justify.	Firm has submitted that it was typo error and concentration of both sample and standard preparation 0.01mg/ml. they also submitted corrected and revised testing method. Firm has also submitted calculation formula.
11.	3.2.P.8	• Justify the weight of standard in assay test with respect to the analytical procedure for assay test. • Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that this mistake was due to typo error in the testing method which has now been rectified. Firm has submitted rectified testing method wherein the standard preparation in the dissolution test has mentioned that "take accurately weighed Dexlansoprazole working standard (on anhydrous basis) equivalent to 50mg" ***However, the raw data sheets have clearly mentioned 30mg which is not justified by the firm.*** Firm has submitted revised stability data sheets with inclusion of API lot number. ***Not submitted.*** ***Not submitted.***

	• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	***Not submitted.***
Decision: Deferred for following: • **Justification for variation in the standard solution concentration as declared n raw data sheets from that mentione din the drug oridyct analytical oricedure for Assay & Dissolution test.** • **Justification for variation in calculation formula applied in the raw data sheet from that mentioned in the drug product analytical procedure for Assay test.** • **Clarification for variation in the API lot# mentioned in the stability summary sheet from that declared on the drug substance COA.** • **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**		
927.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 368; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 788738343417 dated 16/11/2022.
	The proposed proprietary name / brand name	**Gabstar 50mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …….……50mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Other Analgesics and *Antipyretics.*
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 50mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 048725
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.

		Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (PBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)
	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Gabica 50mg Capsules, Batch No. 244C28, mfg. date 03-2022 manufactured by M/s Getz Pharma, by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable. CDP is also performed against the same brand that is Gabica 50mg Capsules, Batch No. 244C28, mfg. date 03-2022 manufactured by M/s Getz Pharma, in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.
API Lot No.	PBF/K/21/0014

Description of Pack (Container closure system)	Alu/Alu Blister strips of 2x7 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T072	T076	T077
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.
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 by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 17180803563 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of

		• Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.	Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.
5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer.*
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.
8.	3.2.P.2.2	Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Lyrica is an innovator of pregabalin capsule. In local market at the time of study only Lyrica 75mg capsule is available so we have chosen another market leader for performing CDP that is Gabica 50mg capsule manufactured by Getz Pharma.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved. Submitted.
11.		Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

Decision: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.

928.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 369; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 22232543805 dated 16/11/2022.
	The proposed proprietary name / brand name	Gabstar 75mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ……..……75mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Analgesics and *Anticonvulsant drug.*
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 75mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 047365
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India. Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (KBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)
	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator brand that is Lyrica 75mg Capsules, Batch No. EY7448, mfg. date 01-2021 manufactured by M/s Pfizer Pharma, Germany by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable. CDP is also performed against the same brand that is Lyrica 75mg Capsules, Batch No. EY7448, mfg. date 01-2021 manufactured by M/s Pfizer Pharma, Germany in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.		
API Lot No.	KBF/K/21/0014		
Description of Pack (Container closure system)	Alu/Alu Blister strips of 2x7 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T071	T074	T075
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
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)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.
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 by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 306443220047 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted. • Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.
5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer.*
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.

8.	3.2.P.2.2	Evidence of the pack of the innovator product shall be submitted.	Firm has submitted evidence of the innovator product with same batch number and manufacturing date as mentioned in CDP and PE.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved. Submitted.
11.		Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

- **Decision: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.**

929.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 370; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 908689580 dated 16/11/2022.
	The proposed proprietary name / brand name	Gabstar 100mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ……100mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Analgesics and *Anticonvulsant drug.*
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 100mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 047366
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021

		Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India. Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (KBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 24 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)
	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Gabica 100mg Capsules, Batch No. 165C26, mfg. date 02-2022 manufactured by M/s Getz Pharma, by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable. CDP is also performed against the same brand that is Gabica 100mg Capsules, Batch No. 165C26, mfg. date 02-2022 manufactured by M/s Getz Pharma, in Acid media

		(pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.		
API Lot No.		KBF/K/21/0014		
Description of Pack (Container closure system)		Alu/Alu Blister strips of 2x7 Capsules packed in unit carton.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 3 months Accelerated: 3 months		
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T073	T078	T079
Batch Size		1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date		06-2022	06-2022	06-2022
Date of Initiation		30-06-2022	30-06-2022	30-06-2022
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)	NA		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.		
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 by the Evaluator:				

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 061760215445 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted. • Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.
5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer.*
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.
8.	3.2.P.2.2	Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Lyrica is an innovator of pregabalin capsule. In local market at the time of study only Lyrica 75mg capsule is available so we have chosen another market leader for performing CDP that is Gabica 50mg capsule manufactured by Getz Pharma.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved. Submitted.
11.		Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

Decision: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.		
On the recommendations of panel of experts, the CLB in its 273rd meeting held on 15th January, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following four sections: i. Tablet Section (General) ii. Capsule Section (General) iii. Sachet Section (General) iv. Dry powder injection section (pre-lyophilized) vial		
930.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, 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. 33812: dated 23-11-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 36831550261 dated 22/11/2022.
	The proposed proprietary name / brand name	**Metzole 500mg/100ml infusion.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains; Metronidazole ……..….5mg
	Pharmaceutical form of applied drug	Intravenous infusion.
	Pharmacotherapeutic Group of (API)	Imidazole derivatives.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Metronidazole 500 mg/100ml (5mg/ml) solution for infusion, MHRA Approved.
	For generic drugs (me-too status)	Flagyl 500mg/100ml Infusion by M/s Sanofi-aventis Pakistan Ltd., Reg. No. 005102.
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020. General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized) Vial.
	Evidence of approval of manufacturing facility/ approved section from Licensing Authority.	Liquid injectable – Ampoule & Vial (General) section is approved vide letter No. F.1-1/2016/Lic. Dated 22-09-2021.
	Name and address of API manufacturer.	AARTI drugs Limited., Plot # 2902-2904 to 2605-2509 GIDC., Sarigam city, Dist. Valsad, Gujrat State, India. Copy of GMP certificate No. 19021202 dated 15-02-2019 issued on the basis of inspection conducted on 14-02-2019 by Food and Drug Control Administration, Gujrat State India is submitted. Valid till 14-02-2022.
	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 Metronidazole is present in USP/BP. Firm has submitted detail of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (Batch No. MTZ/1030410, mfg. date 02-2021), justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches (MTZ/6010028, MTZ/6010029 & MTZ/6010030)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, 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 Flagyl 500mg/100ml Infusion batch No. AW132 manufactured by M/s Sanofi-aventis Pakistan Ltd., by performing quality tests (pH, endotoxin test, 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	AARTI drugs Limited., Plot # 2902-2904 to 2605-2509 GIDC., Sarigam city, Dist. Valsad, Gujrat State, India.		
API Lot No.	MTZ/1030410.		
Description of Pack (Container closure system)	100ml glass Vial containing clear solution.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	500 BT-001	500 BT-002	500 BT-003
Batch Size	500	500	500
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	02-02-2022	02-02-2022	02-02-2022
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.	Copy of GMP certificate No. 19021202 dated 15-02-2019 issued on the basis of inspection conducted on 14-02-2019 by Food and Drug Control Administration, Gujrat State India is submitted. Valid till 14-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.17796/2021/DRAP dated 23/11/2021 is submitted wherein the permission to import different APIs including Paracetamol and Metronidazole BP for the purpose of test/analysis and stability studies is granted. Certificate is attested by the Assistant Director I&E, DRAP, Lahore.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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 by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of drug product manufacturer shall be submitted.	Copy of GMP certificate No. 248/2022-DRAP (AD-0835218-1099) dated 13-12-2022 issued on the basis of inspection conducted on 05-12-2022.
2.	1.5.6	This section has mentioned USP specifications for the drug product while 3.2.P.1 has mentioned BP specifications. Justification shall be submitted.	Firm has submitted revised 3.2.P.1 wherein they have mentioned USP specifications.
3.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer issued by concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. 22023147 issued by Food and drug Control Administration, Gujrat State India in the name of M/s AARTI drugs Limited., Plot # 2902-2904 to 2605-2509 GIDC., Sarigam city, Dist. Valsad, Gujrat State, India on the basis of inspection conducted on 02-02-2022 valid till 17-02-2025.
4.	2.3.R	Revised table for literature references with correct information regarding both the drug substance and drug product with applicable fee shall be submitted.	Firm has submitted revised table for literature references with correct information along with submission of applicable fee of 7500/- vide slip No. 98333729655 dated 06-03-2023.
5.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.	Submitted. *However, the drug substance manufacturer has provided BP specifications while drug product manufacturer has provided USP specifications.*
6.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted. *Analytical procedures as per USP monograph are provided while the drug substance is having BP specifications.*
7.	3.2.S.4.3	Justification shall be submitted for using USP method for the verification studies of the drug substance while the drug substance has BP specifications.	Firm has submitted that BP method used UV method for assay determination while USP use HPLC for assay determination. Since HPLC is more advanced and comprehensive instrument therefore we use USP

			method and specifications for assay determination and other tests.
8.	3.2.S.4.4	Neither the drug substance manufacturer nor the finished product manufacturer has performed bacterial endotoxin test and total aerobic count test. Justify.	Firm has submitted that BP and USP does not include BET and total aerobic test at raw material stage. Both tests are included at the finished product and both tests are performed by us at finished product stage.
9.	3.2.S.5	COA and details of the working standard used in the development studies shall be submitted.	Submitted.
10.	3.2.P.5.1	• Specification has mentioned assay as per innovator specifications. Clarify. • Specification of the finished product has not mentioned identification test. Clarify.	Firm has submitted that it was typographic error and also submitted revised specifications. Revised specifications has also mentioned identification test.
11.	3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization of the applied formulation.	Firm has submitted that BMR of the product has description of terminal sterilization @ 121˚C at 15 PSI. *However, the standard manufacturing process provided by the firm has mentioned that sterilize the rubber plugs, machine parts, Uniforms, S Gloves & dusters in autoclave at 121˚C for half hour followed by one-hour dry cycle as per SOP. Sterilize the glass vials in dry heat sterilizer at 250˚C for two hours as per SOP.* *No terminal sterilization is mentioned in the standard manufacturing process.*
12.	3.2.P.5.2	Analytical procedure for all the test of finished product shall be submitted.	*Firm has once again submitted analytical procedure for assay test in details while no details for other tests are provided.*
13.	3.2.P.8	Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted audit trial reports for the applied formulation.

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.**
- **Firm shall submit comlete batch manufacturing records fo first three commercial batches including the process of terminal sterilisation.**

931.	Name, address of Applicant / Marketing Authorization Holder	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31014; dated 01/11/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 949224949258 dated 22/08/2022.
	The proposed proprietary name / brand name	**Rescar 1% w/w Cream.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Silver Sulfadiazine ……..…10mg
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	D06B Chemotherapeutics For Topical Use.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	20gm and 50gm.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Silvadene 1% (Silver Sulfadiazine) cream, USFDA approved.
	For generic drugs (me-too status)	Quench 1% cream, Ferozsons laboratory, Reg. No. 013090.
	GMP status of the Finished product manufacturer	New License issued on 14-09-2021.
	Evidence of section approval.	Cream/Ointment section (general) approved vide No. F 1-7/2012-Lic dated 14-09-2021.
	Name and address of API manufacturer.	M/s Shenyang Funing Pharmaceutical Co., Ltd. No.115, Hushitai North street, Shenbeixinqu, Shenyang China. Copy of GMP certificate No. LN20160005 issued by CFDA in the name of M/s Shenyang Funing Pharmaceutical Co., Ltd. Dated 12-01-2016 valid till 11-01-2021 is submitted.
	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 Silver sulfadiazine is present in USP. Firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for organic impurities, specifications, analytical procedures and its verification, batch analysis (B. No. 20210801, mfg. date, 11-08-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C±2˚C / 75% ± 5% RH for 6 months. Batches: (20171201, 20171202 &20171203)
	Module-III (Drug Product):	Official monograph of the applied formulation is present in USP. Firm has submitted detail of the drug product including its description, composition, manufacturer, 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 Quench 1% cream, Batch No. 4401,

		Mfg. date 03-2022 manufactured by Ferozsons Laboratory by performing quality tests (Identification, pH and 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 Shenyang Funing Pharmaceutical Co., Ltd. No.115, Hushitai North street, Shenbeixinqu, Shenyang China.		
API Lot No.	20210801.		
Description of Pack (Container closure system)	Aluminum tube packed in unit carton (1's , 20gram).		
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.	CR-01/R20	CR-02/R20	CR-03/R20
Batch Size	237 tubes.	237 tubes	237 tubes
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	16-03-2022	16-03-2022	10-03-2022
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)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. LN20160005 issued by CFDA in the name of M/s Shenyang Funing Pharmaceutical Co., Ltd. Dated 12-01-2016 valid till 11-01-2021 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.5	Revise pharmacological group as per WHO ATC code with submission of applicable fee.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	

	3.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.
	4.	3.2.S.4.2	• Analytical procedures for the drug substance by the drug product manufacturer shall be submitted. • Mobile phase, Composition of the diluent, wave length of the detector, flow rate in the assay test of analytical procedure provided by the Drug Substance manufacturer is different from USP. Clarification shall be submitted.
	5.	3.2.S.4.3	Analytical method verification protocol shall be submitted.
	6.	3.2.S.4.4	• COA of the drug substance provided by the drug product manufacturer has no test for content of nitrate and silver content. Clarification shall be submitted. • COA of the drug substance provided by the drug product manufacturer has supplier name of Mansoor Chemicals. Justification shall be submitted.
	7.	3.2.S.5	Details and COAs of the working standard used in the development of trial batches shall be submitted.
	8.	3.2.P.5.2	• Calculation formula for assay in the analytical procedure for the finished product is different from USP. Clarify. • Analytical procedures for all the test of the finished product shall be submitted.
	9.	3.2.P.5.3	• Minimum fill and microbial enumeration test are not performed in the provided COA of trial batches. • COAs of the finished product are for Adapalene instead of silver sulfadiazine. Clarification shall be submitted.
	10.	3.2.P.8	• Submitted chromatograms does not reflect any wave length, injection volume etc. • Submitted chromatograms also does not reflect any resolution between sulfadiazine and sulfamerazine as required by the official monograph. • Justification shall be submitted for two different form of chromatograms. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.			
932.	Name, address of Applicant / Marketing Authorization Holder		M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.		M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant		☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34507; dated 29/11/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.19942923 dated 25/11/2022.
	The proposed proprietary name / brand name	Pime-4 500mg Injection.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime ……..…….500mg
	Pharmaceutical form of applied drug	Dry powder injection.
	Pharmacotherapeutic Group of (API)	01DE Fourth-generation cephalosporin
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	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	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) - New section vide No.F.1-10/2012-Lic dated 07-06-2022 is approved.
	Name and address of API manufacturer.	M/s 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. 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 Cefepime HCl and L-Arginine is present in USP. 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 and its verification, batch analysis (CEIV/B2201004, mfg. date 11-2022) 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: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)

	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 Cefstar 500mg IV/IM injection by performing quality tests (Identification, Average weight content & 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 Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, India.		
API Lot No.	CEIV/B2201004.		
Description of Pack (Container closure system)	1x10ml vial containing Cefepime HCl with L-Arginine with reconstituent Diluent (WFI).		
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.	TCH001	TCH002	TCH001
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	06-05-22	07-05-22	08-05-22
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 GMP certificate No. New-WHO-GMP/Cert/KD/89275/2020/11/33788 dated 20-10-2020 issued on the basis of inspection conducted on 06-03-2020 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 clearance certificate No. E-897164883689 dated 19-04-2022 for 50Kg of Cefepime HCl and L-Arginine sterile USP having Batch No. CEIV/B2201004 with manufacturing date of 01-11-2021 issued in name of M/s Medisave attested by AD I&E DRAP, Lahore. Firm has also submitted copy of loan letter from M/s Medisave Pharmaceutical for 05kg.
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 by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Latest GMP certificate/last inspection report conducted within last three years for the Finished Product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 70/2021-DRAP (FID/2061717-540) dated 08-09-2021 issued on the basis of inspection conducted on 08-09-2021.
2.	2.3.R	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia with applicable fee.	*Not submitted.*
3.	3.2.S.4.1	Drug Substance manufacturer has mentioned L-arginine quantity (on as is basis) between 34% - 44% while FPP has mentioned 37.1% - 44%. Clarify.	Firm has submitted that it was typographic error and also submitted corrected specification and corrected COA for the drug substance. *However, fee applicable to pre-registration variation is not submitted.*
4.	3.2.S.4.2	Calculation formula for assay of drug substance shall be provided.	Submitted.
5.	3.2.S.4.4	• Justification shall be submitted regarding the COA of the drug substance provided by the drug product manufacturer as assay of Cefepime base on as is basis in the same is 50.19% while the specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5%. • COA of the drug substance by the drug product manufacturer has manufacturing date of 11-2022 while that of the drug substance manufacturer has manufacturing date of 11-2021. Clarify.	Firm has only submitted COA of the drug substance from supplier. *However, initially submitted specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5% while the COA of the finished product manufacturer has assay of Cefepime on as is basis of 50.19 which is out of specifications.* Firm has submitted that it was typo error and they also provided corrected COA.
6.	3.2.P.2.2	• Justification shall be submitted for not performing Pharmaceutical Equivalence against the innovator product. • Details of the reference product used in the Pharmaceutical Equivalence shall be submitted. • pH test is not performed. • Justification shall be submitted for not performing most of the quality test applicable on powder for injection.	Firm has submitted that due to easy availability of market sample Cefstar injection was used in PE. CefStar 500mg Injection, Batch No. C7100, Mfg. date 03-2021 is submitted. Firm has submitted revised results for pharmaceutical equivalence wherein they have added pH test. Not submitted.
7.	3.2.P.8	In use stability data shall be submitted.	Firm has submitted that its ready to use injection.

Decision: Deferred for following:

- **Revised table for literature references with inclusion of status of the both drug substance and finished product in different pharmacopoeias shall be submitted.**
- **Justification shall be submitted for use of out of specifications drug substance in the trial batches.**
- **Submission of Pharmaceutical Equivalence against the innovator product.**
- **Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

933.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34508; dated 29/11/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.63776342 dated 25/11/2022.
	The proposed proprietary name / brand name	**Pime-4 1gm Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine eq. to Cefepime ……..…….1000mg
	Pharmaceutical form of applied drug	Dry powder injection.
	Pharmacotherapeutic Group of (API)	01DE Fourth-generation cephalosporin
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	MAXIPIME 500mg & 1gm (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	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Evidence of section approval.	Dry Powder Injection (Cephalosporin) - New section vide No.F.1-10/2012-Lic dated 07-06-2022 is approved.
	Name and address of API manufacturer.	M/s 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. 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 Cefepime HCl and L-Arginine is present in USP. 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 and its verification, batch analysis (CEIV/B2201004, mfg. date 11-2022) 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: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	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 Cefstar 1000mg IV/IM injection by performing quality tests (Identification, Average weight content & 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 Kopran Research Laboratories Limited, K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, India.		
API Lot No.	CEIV/B2201004.		
Description of Pack (Container closure system)	1x10ml vial containing Cefepime HCl with L-Arginine with reconstituent Diluent (WFI).		
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.	TCP001	TCP002	TCP001
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	28-04-22	29-04-22	30-04-22
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 GMP certificate No. New-WHO-GMP/Cert/KD/89275/2020/11/33788 dated 20-10-2020 issued on the basis of inspection conducted on 06-03-2020 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 clearance certificate No. E-897164883689 dated 19-04-2022 for 50Kg of Cefepime HCl and L-Arginine sterile USP having Batch No. CEIV/B2201004 with manufacturing date of 01-11-2021

		issued in name of M/s Medisave attested by AD I&E DRAP, Lahore. Firm has also submitted copy of loan letter from M/s Medisave Pharmaceutical for 05kg.
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 by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Latest GMP certificate/last inspection report conducted within last three years for the Finished Product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 70/2021-DRAP (FID/2061717-540) dated 08-09-2021 issued on the basis of inspection conducted on 08-09-2021.
2.	2.3.R	Table for literature references shall be revised with inclusion of status of both drug substance and finished product in pharmacopoeia with applicable fee.	*Not submitted.*
3.	3.2.S.4.1	Drug Substance manufacturer has mentioned L-arginine quantity (on as is basis) between 34% - 44% while FPP has mentioned 37.1% - 44%. Clarify.	Firm has submitted that it was typographic error and also submitted corrected specification and corrected COA for the drug substance. *However, fee applicable to pre-registration variation is not submitted.*
4.	3.2.S.4.2	Calculation formula for assay of drug substance shall be provided.	Submitted.
5.	3.2.S.4.4	• Justification shall be submitted regarding the COA of the drug substance provided by the drug product manufacturer as assay of Cefepime base on as is basis in the same is 50.19% while the specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5%. • COA of the drug substance by the drug product manufacturer has manufacturing date of 11-2022 while that of the drug substance manufacturer has manufacturing date of 11-2021. Clarify.	Firm has only submitted COA of the drug substance from supplier. *However, initially submitted specification provided by the drug substance manufacturer has assay limit of Cefepime on as is basis of NLT 50.5% while the COA of the finished product manufacturer has assay of Cefepime on as is basis of 50.19 which is out of specifications.* Firm has submitted that it was typo error and they also provided corrected COA.
6.	3.2.P.2.2	• Justification shall be submitted for not performing Pharmaceutical Equivalence against the innovator product. • Details of the reference product used in the Pharmaceutical Equivalence shall be submitted. • pH test is not performed. • Justification shall be submitted for not performing most of the quality test applicable on powder for injection.	Firm has submitted that due to easy availability of market sample Cefstar injection was used in PE. CefStar 500mg Injection, Batch No. C7100, Mfg. date 03-2021 is submitted. Firm has submitted revised results for pharmaceutical equivalence wherein they have added pH test. Not submitted.
7.	3.2.P.8	In use stability data shall be submitted.	Firm has submitted that its ready to use injection.

Decision: Deferred for following:

- **Revised table for literature references with inclusion of status of the both drug substance and finished product in different pharmacopoeias shall be submitted.**
- **Justification shall be submitted for use of out of specifications drug substance in the trial batches.**
- **Submission of Pharmaceutical Equivalence against the innovator product.**
- **Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

934.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Name, address of Manufacturing site.	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35671; dated 08/12/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.5927268930 dated 10/08/2022.
	The proposed proprietary name / brand name	**Fusigen-G Cream.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Betamethasone as dipropionate……. 0.5mg (0.05% w/w) Gentamicin as Sulphate ……..... 1mg (0.1% w/w)
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	Betamethasone dipropionate (Corticosteroids) Gentamicin Sulphate (Antibiotic)
	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	Mibetin 1 mg/g + 0.5 mg/g Cream, MHRA approved. *One gram of cream contains 1 mg gentamicin (as 1.67 mg gentamicin sulfate) and 0.5 mg betamethasone (as 0.64 mg betamethasone dipropionate).*
	For generic drugs (me-too status)	Gentanix-B Cream, Biogen pharma, Reg. No. 070201.
	GMP status of the Finished product manufacturer	Not provided.
	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	**Betamethasone dipropionate;** Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India. Copy of GMP certificate No. 12/55-2Drug1-2020/7030 dated 26-10-2020 issued by the FDA, Haryana, Panchkula valid till 12-09-2022 is submitted. **Gentamicin Sulfate:** Sichuan Long March Pharmaceutical Co., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China. Copy of GMP certificate No. SC20160076 issued by CFDA, dated 23-02-2017 valid till 22-02-2022 is submitted.
	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)	**Betamethasone Dipropionate** is present in USP. Firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (MLBDP-010221, mfg. date 02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance. **Gentamicin Sulfate** is present in EP/USP. Firm has submitted detail of drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (SC-GM-20220408, mfg. date 02-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: **Gentamicin Sulfate**: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (SC-GM-20140803, SC-GM-20140901 & SG-GM-20140902) **Betamethasone dipropionate:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MLBDP150814, MLBDP-160814 & MLBDP170814). 15
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, 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 comparator product that is Gentanix Cream manufactured by Biogen Pharma by performing quality tests (Identification, Average weight, Uniformity of dosage form & Assay).
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	**Betamethasone dipropionate;** Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India. **Gentamicin Sulfate:** Sichuan Long March Pharmaceutical Co., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China.
API Lot No.	Not submitted.
Description of Pack (Container closure system)	White colour cream filled in aluminum tube.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 Tubes.	500 Tubes.	500 Tubes.
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted that their manufacturing facility is newly licensed hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Betamethasone dipropionate;** Mahima Life Sciences Pvt. Ltd., BST Road, Ganaur District Sonepat, Haryana, India. Copy of GMP certificate No. 12/55-2Drug1-2020/7030 dated 26-10-2020 issued by the FDA, Haryana, Panchkula valid till 12-09-2022 is submitted. **Gentamicin Sulfate:** Sichuan Long March Pharmaceutical Co., Ltd., No. 448 Changqing Road, Central city district, Leshan Sichuan, Province, People's Republic of China. Copy of GMP certificate No. SC20160076 issued by CFDA, dated 23-02-2017 valid till 22-02-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not 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:

- Documents for the procurement of API with approval from DRAP for both the drug substances shall be submitted.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML for Biogen life sciences shall be submitted.	Firm has submitted copy of DML No. 000911 in the name of M/s Biogen Pharmaceuticals w.e.f. 13-02-2020and also provided change of title vide letter No. F. 1-2/2019-Lic. Dated 18-03-2021 from M/s

			Biogen Pharmaceuticals to M/s Biogen Life Sciences.
		• Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences shall be submitted.	***Not submitted.***
2.	1.3.5	Evidence of section approval letter of Biogen Life Sciences shall be submitted.	Firm has submitted copy of section approval vide letter No. F. 1-2/2019-Lic. Dated 14-02-2020 wherein they have cream general section.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted that proposed pack size is 1's.
4.	1.6.5	Valid copy of GMP certificate of both the Drug Substance manufacturer shall be submitted.	**Gentamicin Sulfate:** Firm has once again submitted the same copy of GMP certificate No. SC20160076 issued by CFDA, dated 23-02-2017 valid till 22-02-2022. *Valid copy of GMP certificate shall be submitted.* **Betamethasone dipropionate:** No GMP certificate is submitted.
5.	3.2.S.4.1	• Specification of drug substance i.e. betamethasone by drug product manufacturer shall be submitted.	Submitted.
		• Specification of drug substance i.e. Gentamicin Sulfate by drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.2	• Analytical procedures of drug substance i.e. betamethasone by drug product manufacturer shall be submitted.	Firm has submitted analytical procedures for both the drug substances i.e. betamethasone dipropionate and gentamicin sulfate as per USP specifications.
		• Analytical procedures of drug substance i.e. Gentamicin Sulfate by drug product manufacturer shall be submitted.	
7.	3.2.S.4.3	• Verification studies of the drug substance i.e. betamethasone performed by drug product manufacturer shall be submitted.	Submitted.
		• Verification studies of the drug substance i.e. Gentamicin Sulfate performed by drug product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.4	• Batch analysis of the drug substance i.e. betamethasone provided by the drug substance manufacturer has assay test on UV while official monograph has mentioned HPLC. Clarification shall be submitted.	*No justification submitted.*
		• COA for the drug substance Gentamicin Sulfate provided by the finished product manufacturer has not performed water content, Sulfate content and optical rotation test on the drug substance. Clarification shall be submitted.	Firm has submitted new COA from both the drug substance manufacturer and drug product manufacturer for gentamicin sulfate (B. No. SC-GM-20200202, mfg. date 08-02-2020). *However, the batch No. and manufacturing date of the submitted COA are different from initially submitted COA.*
		• COA for drug substance i.e. Gentamicin Sulfate from drug substance manufacturer is overwritten with respect to mfg. date, release date & expiration date. Justification shall be submitted for this overwriting of COA.	*No justification is submitted by the firm against this point.*
9.	3.2.S.4.5	Details and COA of the working standard of both the drug substances shall be submitted.	Firm has only submitted COA of the working standard for Betamethasone dipropionate. *No details and COA of the working standard for gentamicin sulfate is provided.*
10.	3.2.S.7.3	Stability for the drug substance i.e. Gentamicin Sulfate from concerned	*Firm has once again submitted the same stability data.*

		manufacturer shall be submitted as the submitted one is from Long March Pharm.	
11.	3.2.P.5.1	Qualitative composition of the applied formulation is different from reference product.	Firm has submitted that formulation mentioned in CTD trial base. The actual formulation is mentioned in BMR. *However, no clear justification is provided by the firm.*
12.	3.2.P.2.2	• Justification for not performing PE against the innovator product	Firm has submitted that Gentanix cream manufactured by Biogen pharma was easily available that's why they used the same in PE. Batch No. 2374, Mfg. date 11-2021 & Exp. date 11-2023.
		• No details of the comparator product are submitted in PE.	
13.	3.2.P.5.3	Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.	Submitted.
14.	3.2.P.5.4	Submitted COAs have no pH test on the finished product. Justify.	*No justification is submitted by the firm.*
15.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting with inclusion of API lot number and batch size.	Firm has submitted stability data sheets as per decision of 293rd meeting with submission of batch size and API lot number (500 tubes each & 200507FB for betamethasone dipropionate & SC-GM-20200202 for gentamicin sulfate). *However, the newly provided stability data sheets have different values than the originally submitted. Furthermore, the API lot members mentioned are also different from the batch analysis provided in original dossiers.*
		• Justify the wave length applied in the submitted chromatograms with respect to the analytical procedures. Analytical procedures have mentioned 254nm while submitted chromatograms reflects 240nm.	*No justification submitted against this point.*
16.		• Documents for the procurement of API with approval from DRAP for both the drug substances shall be submitted.	Firm has submitted copy of commercial invoice No. M/21-22/132 dated 03-03-2021 wherein M/s Biogen Life Sciences have imported 0.020kg of betamethasone dipropionate with batch No. 2005207 FB, mfg. date 12-2020. *However, in the submitted document invoice date, Consignee/buyer name, Batch number manufacturing date etc. all are over written and changed from original ones. Furthermore, DRAP attested clearance is not provided for the same.* Copy of commercial invoice No. 21584234 dated 12-24-2021 mentioning 0.5kg quantity of gentamicin Sulfate, batch No. SC-GM-20200202, mfg. date 02-08-2020 is submitted. *Similar to the above mentioned document, this document is also over written and no clearance certificate from DRAP is submitted.*
			Not submitted.
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	*Submitted.*
		• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
17.	3.2.R	Blank master production document /batch manufacturing record to be used during the commercial manufacturing of the applied	Submitted.

	product along with copies of executed BMRs shall be submitted.

Decision: Deferred for following;

- **Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences.**
- **Valid copy of GMP certificate of both the Drug Substance manufacturer shall be submitted.**
- **Justification for the batch analysis of the drug substance i.e. betamethasone shall be submitted as drug substance manufacturer has assay test on UV while official monograph has mentioned HPLC.**
- **Justification shall be submitted regarding the batch number and manufacturing date of the COA submitted initially and COA submitted in replies as both are different from each other.**
- **Details and COA of the working standard i.e. Gentamicin sulfate drug substances shall be submitted.**
- **Justification shall be submitted for difference in qualitative composition of the applied formulation from innovator product.**
- **Pharmaceutical equivalence against the innovator product shall be submitted.**
- **Justification shall be submitted regarding the change in results of tests in stability data sheets that were initially submitted and that submitted in reply.**
- **Justification shall be submitted regarding the API lot number as the batch analysis has mentioned some other batch number while the newly submitted stability data sheets have some other lot number.**
- **Justify the wave length applied in the submitted chromatograms with respect to the analytical procedures. Analytical procedures have mentioned 254nm while submitted chromatograms reflects 240nm.**
- **Documents for the procurement of API with approval from DRAP for betamethasone dipropionate drug substances shall be submitted.**
- **Documents for the procurement of API with approval from DRAP for gentamicin Sulfate drug substances shall be submitted.**

935.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Name, address of Manufacturing site.	M/s Biogen life Sciences, 8-KM chekbeli Road Rawat Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 605; dated 06/01/2023.
	Details of fee submitted	PKR 30,000/-: vide slip No.16403533322 dated 14/07/2022.
	The proposed proprietary name / brand name	Montigen 4 mg Sachet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains; Montelukast as sodium …….... 4 mg
	Pharmaceutical form of applied drug	Oral Granules in sachet.
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SINGULAIR® (montelukast sodium) oral granules, USFDA Approved.
	For generic drugs (me-too status)	Montekast Sachet 4mg, Legacy Pharmaceuticals, Reg. No. 049906
	GMP status of the Finished product manufacturer	Not provided.

	Evidence of section approval.	Not provided.
	Name and address of API manufacturer.	M/s Dhanuka Laboratory Ltd., Plot No., SP4-4 Industrial Area Keshwana Rajput Kotputli Shahpura, Dist. Jaipur Rajasthan, 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 Montelukast Sodium is present in USP. 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 and its verification, batch analysis (MTS/1907004, mfg. date 07-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batches: (MLS-F#009/15, MLS-F#010/15 & MLS-F#011/15) MLS-F#O10/15
	Module-III (Drug Product):	Official monograph for Montelukast sodium oral granules is present in USP. Firm has submitted detail of the drug product regarding its description and composition, 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 innovator that is Singular 4mg Sachet, batch No. 21A601 of Merck Research Laboratories by performing quality tests (Average weight, Dissolution, Assay, Content Uniformity). Comparative Dissolution is also performed against the same brand that is Singular 4mg Sachet by Merk reasarch laboratories 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 Dhanuka Laboratory Ltd., Plot No., SP4-4 Industrial Area Keshwana Rajput Kotputli Shahpura, Dist. Jaipur Rajasthan, India.
API Lot No.	MTS-1907004.
Description of Pack (Container closure system)	Montigen is filled in sealed printed foil sachet 14 sachets are pack in unit carton with 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: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-002	
Batch Size	4000 Sachet	4000 Sachet	
Manufacturing Date	04-2022	04-2022	
Date of Initiation	25-04-2022	25-04-2022	
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)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice No. SOK/EXP1920/0059 dated 19-11-2019 mentioning 5kg of Montelukast sodium USP, Batch No. MTS/1907004, mfg. date 07-2019 attested bi Assistant Director, I&E, DRAP, Islamabad. Invoice has mentioned Seraph pharmaceuticals as importer of the material.
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 by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML for Biogen life sciences shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years of Biogen life sciences shall be submitted.	
2.	1.3.5	Evidence of section approval letter of Biogen Life Sciences shall be submitted.	
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	
4.	1.6.5	Valid copy of GMP certificate of the Drug Substance manufacturer shall be submitted.	
5.	2.3.R	• Table for literature references has not mentioned status of drug substance in all pharmacopoeias i.e.JP. Revised table for literature references with applicable fee shall be submitted.	

6.	3.2.S.4.1	Specification of drug substance by drug substance manufacturer shall be submitted.
7.	3.2.S.4.2	Analytical procedures in USP has mentioned up to 16 minutes' time for assay of drug substance and in enantiomeric purity while the analytical procedure provided by the drug substance manufacturer has mentioned up to 25 minutes. Clarification shall be submitted.
8.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.
9.	3.2.S.5	Details and COA of the working standard used in the development of trial batches shall be submitted.
10.	3.2.P.2.2	• Justification shall be submitted for not performing identification test Pharmaceutical Equivalence. • Tabulated CDP results with all the time points in different medias shall be submitted. • Justification shall be submitted for the provided graphical results of CDP as it has mentioned some other brand names. • Raw data sheets for the CDP results shall be submitted.
11.	3.2.P.5.1	Standard solution in the analytical procedures for the finished drug product in identification, dissolution & assay test is different from official pharmacopoeia. Clarification shall be submitted.
12.	3.2.P.5.3	Complete validation/verification studies of the drug product performed by the drug product manufacturer shall be submitted.
13.	3.2.P.8	• Raw data sheets for both the assay test and dissolution test at each time point with chromatograms shall be submitted. Furthermore, each time point raw data sheets shall be accompanied with calculation formula. • Justification shall be submitted regarding the submitted chromatograms as it does not mention wave length of detector. • Justification shall be submitted regarding submitted chromatograms as it also does not reflect the resolution factor as required by the official monograph. • Complete six-month stability data shall be submitted. • Justification for manufacturing only two batches shall be submitted.
14.		• Clear and readable copy of the clearance certificate for import of raw material shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Log of HPLC run showing change in concentration of mobile phase is required.

	• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
15.	3.2.R Blank master production document /batch manufacturing record to be used during the commercial manufacturing of the applied product along with copies of executed BMRs shall be submitted.	

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case No. 02 Priority Registration applications on the basis of Export Facilitation of locally manufactured Human Drugs applied on form 5F.

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s Atco Laboratories Limited** have achieved the benchmark of more than 100,000 USD **(542854.81 USD)** during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

Following products are presented before the Board in light of the decision of the 133rd meeting of DRAP Authority held on 13th April 2022 for consideration.

936.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5219 dated 24/02/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 3813214571 dated 27/01/2022.
	The proposed proprietary name / brand name	Silodosin 4mg Capsule.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin ……4mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Urological, alpha-adrenoreceptor antagonists. ATC Code: G04CA04
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 60's, 90's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	RAPAFLO® 4mg & 8mg (silodosin) capsules, USFDA approved.
	For generic drugs (me-too status)	Sildat 4mg Capsule, Sami Pharmaceutical, Reg. No. 105264.
	GMP status of the Finished product manufacturer	DML Renewal receipt, dated 17-03-2021 submitted along with previous copy DML w.e.f. 11-04-2016.

		Copy of GMP certificate No. 160/2020-DRAP (K) dated 24-12-2020 on the basis of inspection conducted on 06-11-2020 is submitted by the firm.
	Evidence of section approval.	Capsule general section approved vide letter No. F. No.F.2-5/85-Lic (Vol-VI) dated 23-01-2019.
	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China. Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
	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)	Firm has submitted detail of drug substance regarding its manufacturers, structure, general properties, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis (Batch No. 20092102, mfg. date 21-09-2020) and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20170218, 20170205, 20170212)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturers, description of manufacturing process and controls, Batch formula, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against innovator product that is Rapaflo 4mg Capsule, Batch No. K58138 manufactured by Allergan Inc. Markham by performing quality tests (Identification, disintegration, Dissolution & Assay). Comparative Dissolution is also performed against the same brand in Acid media 0.1 N HCl, Acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. Both applied formulation and reference product shows more than 85% release within 15 minutes hence F2 is not calculated.
	Analytical method validation/verification of product	Method validation studies are submitted including specificity, linearity, accuracy, range, precision and robustness.
STABILITY STUDY DATA		
Manufacturer of API		Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China.

API Lot No.	20092102.		
Description of Pack (Container closure system)	Size "3" hard gelatin capsules with white body and purple cap filled with white to off white granular powder packed in Alu-Alu blister further packed in printed carton (1 x 7's).		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated:06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FE038C.	MA113C.	MA114C.
Batch Size	2500 capsules.	2500 capsules.	2500 capsules.
Manufacturing Date	03-2021.	03-2021.	03-2021.
Date of Initiation	24-03-2021.	24-03-2021.	24-03-2021.
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Rofl 500mcg Tablets" which was conducted on 10-10-2017, and was presented in 277th meeting of Registration Board (27 - 29 December, 2017). Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. ✓ Audit trail reports on the testing were verifiable. Firm has adequate monitoring and controls for stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No. WD20201020 dated 20-10-2020 mentioning 400gm of Silodosin, Batch No. 20092102, mfg. date 21-09-2020 attested by Assistant Director I&E, DRAP, Karachi dated 07-11-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000188 w.e.f. 11-04-2021.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of License No. 20190399 for Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China valid till 31-12-2025.

			License is verified from official website of NMPA and they also have scope of production of silodosin.
3.	2.3.R	Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references wherein they have updated pharmacopoeial status of the drug substance. ***However, fee applicable for pre-registration variation is not submitted.***
4.	3.2.S.4.1	• Specifications of the drug substance from drug substance manufacturer shall be submitted. • Justification shall be submitted regarding most of the specifications of the drug substance provided by both the drug substance manufacturer and finished product manufacturer as they are different from Japanese pharmacopoeia.	Submitted. Firm has submitted revised specifications and COA from both the drug substance and finished product manufacturer as per Japanese pharmacopoeia.
5.	3.2.S.4.2	• Justify the standard preparation and sample preparation in assay test with respect to that of the drug substance standard and test preparation. • Justification shall be submitted regarding the standard preparation and sample preparation in assay test with respect to that of the Japanese pharmacopoeia as final concentration is different.	Firm has submitted that analytical method according to Japanese pharmacopoeia has been adopted and applied on the drug substance analysis. They also submitted analytical methods from both drug substance and finished product manufacturer. ***However, the submitted analytical procedures in the initial dossier the standard and test preparation both are different from drug substance manufacturer and Japanese pharmacopoeia.***
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.7	Justification shall be submitted regarding the container closure system of the drug substance as it is mentioned to be packed in LLDPE while the official monograph has mentioned Well-closed containers. Storage—Light-resistant.	Firm has submitted that drug substance manufacturer has performed stability studies in the same container closure system as marketed previously and now they have adopted Japanese pharmacopoeia specifications. They will provide upcoming consignment according to updated specifications using the same container closure system as recommended by the JP monograph.
8.	3.2.S.7.3	Most of the specifications of the drug substance provided in 3.2.S.4.1 are changed in the stability data sheets. Clarification shall be submitted.	Firm has submitted that drug substance was comply with in house specifications in which critical test required in stability studies were covered and already adopted from Japanese pharmacopoeia. Further relevant section of drug substance part will be updated as attached letter from drug substance manufacturer in section 3.2.S.7.3.
9.	3.2.P.2.2	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equillance.	Firm has submitted that uniformity of dosage unit is a parameter to ensure the consistency of the dosage form. We have performed this test on all stability batches of both applied strength in initial stages to comply with the release requirements and found complies with the established criteria.
10.	3.2.P.8	Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Justify the performance of analytical procedures in volumetric flasks and other glassware without taking this precaution.	Firm has submitted that precaution as recommended for drug substance by JP monograph has been adopted for analysis of drug product and applied the same throughout the development studies of applied product. They also provided updated analytical procedures.
Decision: Deferred for following:			

• **Justification shall be submitted regarding the standard preparation and sample preparation in assay test of the drug substance as it is different from both the drug substance manufacturer method and Japanese pharmacopoeia.** • **Submission of updated stability data for drug substance with revised specifications as recommended by the JP monograph.** • **Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**		
937.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4387; dated 16/02/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 0047238468 dated 27/01/2022.
	The proposed proprietary name / brand name	Silodosin 8mg Capsule.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin ……8mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Urological, alpha-adrenoreceptor antagonists. ATC Code: G04CA04
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 60's, 90's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	RAPAFLO® 4mg & 8mg (silodosin) capsules, USFDA approved.
	For generic drugs (me-too status)	Sildat 8mg Capsule, Sami Pharmaceutical, Reg. No. 105265.
	GMP status of the Finished product manufacturer	DML Renewal receipt, dated 17-03-2021 submitted along with previous copy DML w.e.f. 11-04-2016. Copy of GMP certificate No. 160/2020-DRAP (K) dated 24-12-2020 on the basis of inspection conducted on 06-11-2020 is submitted by the firm.
	Evidence of section approval.	Capsule general section approved vide letter No. F. No.F.2-5/85-Lic (Vol-VI) dated 23-01-2019.
	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China. Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
	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)	Firm has submitted detail of drug substance regarding its manufacturers, structure, general properties, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis (Batch No. 20092102, mfg. date 21-09-2020) and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20170218, 20170205, 20170212)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturers, description of manufacturing process and controls, Batch formula, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against innovator product that is Rapaflo 8mg Capsule, Batch No. K59657 manufactured by Allergan Inc. Markham by performing quality tests (Identification, disintegration, Dissolution & Assay). Comparative Dissolution is also performed against the same brand in Acid media 0.1 N HCl, Acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. Both applied formulation and reference product shows more than 85% release within 15 minutes hence F2 is not calculated.
	Analytical method validation/verification of product	Method validation studies are submitted including specificity, linearity, accuracy, range, precision and robustness.

STABILITY STUDY DATA

Manufacturer of API	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China.		
API Lot No.	20092102.		
Description of Pack (Container closure system)	Size "1" hard gelatin capsules with white body and blue cap filled with white to off white granular powder packed in Alu-Alu blister further packed in printed carton (1 x 7's).		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated:06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA116C.	MA117C.	MA118C.
Batch Size	2666 capsules.	2666 capsules.	2666 capsules.
Manufacturing Date	03-2021.	03-2021.	03-2021.
Date of Initiation	07-04-2021.	07-04-2021.	07-04-2021.
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Rofl 500mcg Tablets" which was conducted on 10-10-2017, and was presented in 277th meeting of Registration Board (27 - 29 December, 2017). Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. ✓ Audit trail reports on the testing were verifiable. Firm has adequate monitoring and controls for stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No. WD20201020 dated 20-10-2020 mentioning 400gm of Silodosin, Batch No. 20092102, mfg. date 21-09-2020 attested by Assistant Director I&E, DRAP, Karachi dated 07-11-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000188 w.e.f. 11-04-2021.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of License No. 20190399 for M/s Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China valid till 31-12-2025. License is verified from official website of NMPA and they also have scope of production of silodosin.
3.	2.3.R	Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references wherein they have updated pharmacopoeial status of the drug substance. *However, fee applicable for pre-registration variation is not submitted.*
4.	3.2.S.4.1	• Specifications of the drug substance from drug substance manufacturer shall be submitted. • Justification shall be submitted regarding most of the specifications of the drug substance provided by both the drug substance manufacturer and finished product manufacturer as they are different from Japanese pharmacopoeia.	Submitted. Firm has submitted revised specifications and COA from both the drug substance and finished product manufacturer as per Japanese pharmacopoeia.
5.	3.2.S.4.2	• Justify the standard preparation and sample preparation in assay test with	Firm has submitted that analytical method according to Japanese pharmacopoeia has been adopted and

		respect to that of the drug substance standard and test preparation. • Justification shall be submitted regarding the standard preparation and sample preparation in assay test with respect to that of the Japanese pharmacopoeia as final concentration is different.	applied on the drug substance analysis. They also submitted analytical methods from both drug substance and finished product manufacturer. *However, the submitted analytical procedures in the initial dossier the standard and test preparation both are different from drug substance manufacturer and Japanese pharmacopoeia.*
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.7	Justification shall be submitted regarding the container closure system of the drug substance as it is mentioned to be packed in LLDPE while the official monograph has mentioned Well-closed containers. Storage—Light-resistant.	Firm has submitted that drug substance manufacturer has performed stability studies in the same container closure system as marketed previously and now they have adopted Japanese pharmacopoeia specifications. They will provide upcoming consignment according to updated specifications using the same container closure system as recommended by the JP monograph.
8.	3.2.S.7.3	Most of the specifications of the drug substance provided in 3.2.S.4.1 are changed in the stability data sheets. Clarification shall be submitted.	Firm has submitted that drug substance was comply with in house specifications in which critical test required in stability studies were covered and already adopted from Japanese pharmacopoeia. Further relevant section of drug substance part will be updated as attached letter from drug substance manufacturer in section 3.2.S.7.3.
9.	3.2.P.2.2	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equillance.	Firm has submitted that uniformity of dosage unit is a parameter to ensure the consistency of the dosage form. We have performed this test on all stability batches of both applied strength in initial stages to comply with the release requirements and found complies with the established criteria.
10.	3.2.P.8	Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Justify the performance of analytical procedures in volumetric flasks and other glassware without taking this precaution.	Firm has submitted that precaution as recommended for drug substance by JP monograph has been adopted for analysis of drug product and applied the same throughout the development studies of applied product. They also provided updated analytical procedures.

Decision: Deferred for following:

- **Justification shall be submitted regarding the standard preparation and sample preparation in assay test of the drug substance as it is different from both the drug substance manufacturer and Japanese pharmacopoeia.**
- **Submission of updated stability data for drug substance with revised specifications as recommended by the JP monograph.**
- **Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s Macter International Limited** have achieved the benchmark of more than 100,000 USD **(461250 USD)** during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

938.	Name, address of Applicant / Marketing Authorization Holder	**M/s Macter International Ltd.,** F-216, S.I.T.E., Karachi - Pakistan.
	Name, address of Manufacturing site.	**M/s Macter International Ltd.,** F-216, S.I.T.E., Karachi - Pakistan.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 37579; dated 23/12/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No.265291594 dated 30/11/2022.
	The proposed proprietary name / brand name	**Trio-Haler DPI Capsule 150mcg + 50mcg + 160mcg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI Capsule Contains: Indacaterol as acetate ……..……...…...150mcg Glycopyrronium (as bromide) …...……50mcg Mometasone Furoate ……160mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains: Indacaterol (as acetate) ….....…….114mcg Glycopyrronium (as Bromide) ……...…46mcg Mometasone Furoate…….136mcg
	Pharmaceutical form of applied drug	**Transparent cap and body, Hypromellose capsule size No. 3 containing white to off white powder.**
	Pharmacotherapeutic Group of (API)	**Adrenergic in combination with anticholinergics incl. triple combinations with corticosteroids (ATC code: R03AL12).**
	Reference to Finished product specifications	Innovators Specifications.
	Proposed Pack size	**30's.**
	Proposed unit price	**As per SRO.**
	The status in reference regulatory authorities	Enerzair Breezhaler 114 micrograms/46 micrograms/136 micrograms inhalation powder, hard capsules (150 mcg of indacaterol (as acetate), 63 mcg of glycopyrronium bromide equivalent to 50 mcg of glycopyrronium and 160 mcg of mometasone furoate) **Novartis Euro pharm Limited,** Ireland, **(EMA Approved).**
	For generic drugs (me-too status)	**INDIBRO-M 150/50/160 mcg DPI Capsule** By **M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi. (DRB 320 approved) Could not be confirmed.**
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 113/2022-DRAP (K) dated 5th August 2022 issued on the basis of inspection conducted on 04-08-2022 is submitted.
	Evidence of section approval.	Encapsulation (Steroid) Including DPI section approved vide letter No. F. 2-13/95-Lic (Vol-VII) dated 10-12-2019.
	Name and address of API manufacturer.	Indacaterol Acetate: **M/s. Melody Healthcare, Plot No. J73 MIDC Tarapur, Boisar Palghar 401506 Maharashtra, India.** **Glycopyrronium Bromide:** M/s Harman Finochem limited, Plot no: E-7, E-8, E-9, MIDC Indl. Area, Chikalthana, Aurangabad-431 006, India. Mometasone Furoate: M/s Aurisco Pharmaceutical Co, Limited, Badu Industrial Park Zone, Tiantai County, Zhejiang Province 317200 P.R. China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	Indacaterol Acetate: Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (ICA/21001M3, mfg. date 10-2021) and justification of specification, reference/working standard, container closure system and stability studies of drug substance. Glycopyrronium Bromide: Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (GCP/003/2018-2019/A, mfg. date 05, 2018) and justification of specification, reference/working standard, container closure system and stability studies of drug substance. Mometasone Furoate: Firm has submitted details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturer, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (A3-211101, mfg. date 11, 2021) and justification of specification, reference/working standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Indacaterol Acetate: Real time: 30°C ± 2°C / 75% ± 5%RH for 9 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (ICA/01/21, ICA/02/21 & ICA/03/21) Glycopyrronium Bromide: Real time: 30°C ± 2°C / 65% ± 5% RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months Batches: (GCP/002/2005-2006, GCP/002/2007-2008 & GCP/008/ 2008-2009) Mometasone Furoate: Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months Batches: (A3-111001, A3-111002 & A3-111003)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**Pharmaceutical Equivalence is established against Innovator Product i.e. Enezair 150/50/160mcg DPI capsule Batch No: BUL36 manufactured by Novartis**

		Pharma by performing identification, particle size distribution by cascade impaction and assay test.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	DPI Device:	**DPI device:** Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB"). **Manufacturer:** Berry Plastiape S.p.A **Shelf Life:** 03 years.

STABILITY STUDY DATA

Manufacturer of API	**Indacaterol Acetate:** **M/s. Melody Healthcare, Plot No. J73 MIDC Tarapur, Boisar Palghar 401506 Maharashtra, India.** **Glycopyrronium Bromide:** M/s Harman Finochem limited, Plot no: E-7, E-8, E-9, MIDC Indl. Area, Chikalthana, Aurangabad-431 006, India. **Mometasone Furoate:** M/s Aurisco Pharmaceutical Co, Limited, Badu Industrial Park Zone, Tiantai County, Zhejiang Province 317200 P.R. China.		
API Lot No.	**Indacaterol acetate: ICA/21001M3** **Glycopyrronium Bromide: GCP/003/2018-2019/A** **Mometasone Furoate: A3-211101**		
Description of Pack (Container closure system)	**Capsules are packed in Alu/Alu blister card further packed in a cardboard 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.	**TH-DPI-01**	**TH-DPI-02**	**TH-DPI-03**
Batch Size	1000 capsules	1000 capsules	1000 capsules
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	03-2022	03-2022	03-2022
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)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Indacaterol acetate:** **Firm has submitted copy of GMP certificate (No. 6100560 dated 09-07-2021 for M/s Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Thane- Zone4.Maharashtra State, India issued by Food & Drugs Administration (Maharashtra State). The Certificate is valid till 08-07-2022.** **Glycopyrronium Bromide:** **Not submitted.** **Mometasone Furoate:** Not Submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Indacaterol acetate:** **Not submitted.** **Glycopyrronium Bromide:**

		Not submitted. **Mometasone Furoate:** **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	Section 1.5 has mentioned solution for injection. Clarification shall be submitted.	Firm has submitted that there was a Typo error in mentioning the proper dosage form i.e., Dry Powder for inhalation in Capsule. They also submitted revised section 1.5 with correct information.
2.	1.5.8	Evidence of approval of applied formulation by DRAP along with brand name, registration number, name of the manufacturer shall be submitted otherwise fee for new drug product shall be submitted.	Firm has submitted differential fee of 45000/- vide slip No. 178703086 dated 10-03-2023.
3.	1.6.5	• Valid copy of the GMP certificate for drug substance Indacaterol acetate issued by concerned/relevant regulatory authority shall be submitted. Further justify how drug substance was procured from a manufacturer which holds Licence to manufacture drugs for purposes of examination, test or analysis.	Firm has submitted copy of GMP certificate No. 6107483 dated 27-06-2022 **for M/s Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Thane- Zone4.Maharashtra State, India issued by Food & Drugs Administration (Maharashtra State). The Certificate is valid till 26-06-2023.**
		• Valid copy of the GMP certificate issued by concerned/relevant regulatory authority for drug substance **Glycopyrronium Bromide** shall be submitted.	Firm has submitted copy of GMP certificate No. WHO-GMP /CERT/AD/82606/2020 /11/31613 dated 14-04-2020 **for** M/s Harman Finochem limited, Plot No: E-7, E-8, E-9, MIDC Indl. Area, Chikalthana, Aurangabad-431 006, India **issued by Food & Drugs Administration, M.S. Bandra (E) Mumbai, India. The Certificate is valid till 13-04-2023.**
		• Valid copy of the GMP certificate issued by concerned/relevant regulatory authority for drug substance **Mometasone Furoate** shall be submitted.	**Firm has submitted copy of written confirmation for active substances exported to EU for M/s** Aurisco Pharmaceutical Co, Limited, Badu Industrial Park Zone, Tiantai County, Zhejiang Province 317200 P.R. China issued by Zhejiang Medical product administration. ***Not issued by relevant authority.***
4.	1.5.14 to 1.5.20	All the commitment/undertaking signed by authorized personnel shall be submitted.	Submitted.
5.	2.3.R	Table for literature references has not mentioned status in different pharmacopoeias for the drug substances. Revised table for literature references for each drug substance with complete pharmacopoeial status with applicable fee shall be submitted.	Firm has submitted revised table for literature references without submission of applicable fee.

6.	3.2.S.4.1	• Specification for the drug substance Indacaterol acetate by the finished product manufacturer shall be submitted.	***Not submitted.***
		• Specification has mentioned assay of Glycopyrronium Bromide 98 – 102% while the stability data sheets has mentioned 98 – 100.5%. Clarify.	Firm has submitted that Glycopyrronium Complies the USP specifications, stability sheets with USP specification are also provided. ***However, no stability sheets are provided.***
		• EP has mentioned 99 – 101% content for Glycopyrronium Bromide while both the drug substance manufacturer and drug product manufacturer has 98 – 102%. Clarification shall be submitted.	Firm has submitted that Glycopyrronium bromide Complies the USP specifications, Raw material monograph for Glycopyrronium Bromide in USP specifies limit for assay between 98 to 102%.
		• Specification of the drug substance Mometasone furoate by the drug substance manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.2	Analytical procedures of the drug substance Mometasone furoate by the drug substance manufacturer shall be submitted.	Submitted.
8.	3.2.S.5	• Details and COA of reference standard/working standard of Mometasone Furoate shall be submitted.	Submitted.
		• Details and COA of reference standard/working standard of Glycopyrronium Bromide shall be submitted.	Submitted.
9.	3.2.S.7	• Complete real time stability data for indacterol acetate shall be submitted.	Firm has submitted 12-months real time and 06 months accelerated stability data for indacterol acetate.
		• Stability data for the drug substance Mometasone Furoate from concerned manufacturer shall be submitted.	Firm has submitted 06-months accelerated and 36-months real time stability for three batches.
10.	3.2.P.1	• Qualitative composition is different from the innovator product as innovator product contains magnesium stearate while applied formulation has no magnesium stearate. Justify.	Firm has submitted that magnesium stearate is used as lubricant in any of the formulation, however in our case no lubricant was used as our particle size was defined and there was no issue pertaining to flow ability.
		• Label claim of each delivered dose in line with the reference product shall also be submitted.	Submitted.
11.	3.2.P.2.2	DDU delivered dose uniformity and uniformity of dosage units are not performed in PE. Justify.	Firm has submitted that invitro Comparative Delivered Dose Uniformity and uniformity of dosage units' study between Enerzair & Trio-Haler was performed and is established in P.2.2.3, unfortunately it was not mentioned in PE Report. They also provided updated pharmaceutical equivalence report wherein they included both the tests.
12.	3.2.P.3.2	Quantities of the active substances in batch formula shall be justified.	Firm has submitted that each capsule contains 150 mcg of indacaterol (as acetate), 63 mcg of glycopyrronium bromide equivalent to 50 mcg of glycopyrronium and 160 mcg of mometasone furoate, whereas there is mistake in typing the document however actual quantity of material been dispensed and processed can be traced through Batch manufacturing record and dispensing sheet, also the results for all batched depicts the result within limits.
13.	3.2.P.5.4	Batch analysis has mentioned 2000 capsules each batch while the stability data sheets	Firm has submitted that there was a typo error in mentioning the batch size in stability data

		have mentioned 1000 capsules each batch. Clarification shall be submitted.	sheets. Actual batch size for all 3 batches are 1000 capsules.
14.	3.2.P.8	• Documents for the procurement of all the three drug substances with approval from DRAP shall be submitted.	Firm has submitted copy of commercial invoice No. MBR2223/GE dated 07-06-2022 mentioning 0.003kg of Indacaterol acetate, Batch No. ICA/21001M3, mfg. date 10-2021. Firm has also submitted computerized clearance certificate No. K-619772283976 with Date of issue: 23-Jun-2022. Firm has submitted copy of commercial invoice No. P/E9/145/2018-19 dated 10-07-2018 mentioning 0.035kg quantity of Glycopyrrolate USP, batch No. GCP/003/2018-2019/A, mfg. date 05-2018, Exp. date 04-2021 attested by Assistant Director I&E, DRAP, Karachi dated 31-07-2018. Firm has submitted copy of commercial invoice No. 22T-075 dated 04-01-2022 mentioning 10kg quantity of Mometasone Furoate, batch No. A3-211101, mfg. date 11-2021. Invoice has mentioned name of M/s Saffron Pharmaceutical as consignee. Firm has also submitted loan letter of API for development purpose from M/s Saffron pharmaceuticals. Submitted.
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Case No. 03 Priority Registration applications on the basis of Export Facilitation of locally manufactured Human Drugs applied on form 5D.

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s Tabros Pharma** have achieved the benchmark of more than 100,000 USD **(575683.20 USD)** during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

939.	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	ELZA/Plafor 10mg Tablet.
	Composition	Each film coated tablet contains: Empagliflozin ……..…… 10mg.

	Diary No. Date of R& I & fee	Dy. No. 15649 dated 20-09-2017, Fee Rs: 50,000/- dated 16.09.2017 vide deposit slip No. 0275713. (Duplicate dossier verified by R&I section.)
	Pharmacological Group	Antidiabetic (Sodium/glucose co transporter 2 (SGLT2) inhibitor.
	Type of Form	Form 5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	Proposed Pack Sizes: 7's, 10's, 14's, 28's, 30's Proposed Price: As per SRO.
	Approval status of product in Reference Regulator Authorities	JARDIANCE® 10mg and 25mg (Empagliflozin film coated tablets), USFDA approved.
	Me-too status	Diampa Tablets 10mg, Getz Pharma, Reg. No. 093073.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Elza 10mg tablets.		
Manufacturer of API	(Empagliflozin) M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China.		
API Lot No.	Empagliflozin: E-20190920-D02-E06-01.		
Description of Pack (Container closure system)	Light yellow colour, round, film coated tablets plain on both sides blistered in Alu-Alu foil packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR001-1/ELZ	TR002-1/ELZ	TR003-1/ELZ
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	01-07.2020	01-07.2020	01-07.2020
No. of Batches	03		
Date of Submission	Dy. No. 9448 dated 26-03-2021.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). 2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. E-20190920-D02-E06-01 Mfg. date 09-11-2019) of the drug substance (Empagliflozin) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China. Firm has also submitted copy of COA with same batch number and manufacturing date.

3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5% RH for 6 months. Batches:(20160606, 20161017 & 20161219).
5.	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 dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone. Valid till 24.08.2023.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. HN200424-L dated 01-12-2019 from exporter M/s Beijing Sino Hanson Import & Export Co., Ltd. No.3, Zhonghe road, Fengtai District, Beijing China, for import of 0.4Kg of Empagliflozin (Batch No. E-20190920-D02-E06-01) in name of M/s Tabros Pharma (Pvt). Ltd., Karachi attested by Assistant Director, DRAP, Karachi dated 21-05-2020. Copy of Form 6 attested by Assistant Director, DRAP, Karachi is attached while Form 3 and Form 7 are also provided.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same ingredients as that of the innovator product, so compatibility studies with excipients are not required.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** TR001-1/ELZ / 1500 Tablets / 15-06.2020 TR002-1/ELZ / 1500 Tablets / 15-06.2020 TR003-1/ELZ / 1500 Tablets / 15-06.2020
11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Elza (Empagliflozin) 10mg Tablet against Jardiance tablet 10mg, Batch No. 905545, Mfg. date 08-2019 manufactured by Boehringer Ingelheim, Germany in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Latest GMP certificate/last inspection report of the finished product manufacturer conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate No. 53/2022-DRAP (K) dated 15-04-2022 issued on the basis of inspection conducted on 07-04-2022.

2.	Justification shall be submitted for the difference of concentration of the reference solution and test solution in the assay test as the drug substance manufacturer has mentioned 0.02 mg/ml strength while drug product manufacturer has mentioned 0.1mg/ml.	Firm has submitted that they have followed the procedure of drug substance for the determination of assay as similar as manufacturer pertaining to chromatographic condition, wave length, flow rate and mobile phase, only concentration is changed 20mcg to 100 mcg/ml, but we kept same concentration of standard and sample comparable/ alike and validated the method as per ICH guideline, Hence it is acceptable.
3.	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of manufacturing license of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China Valid till 27.11.2027.
4.	Justify dissolution parameters i.e. dissolution limits, dissolution medium, Volume of the medium, RPM and wave length applied for the applied formulation i.e., NLT 80% (Q) in 30 minutes and 0.1N HCL medium, medium volume (500ml) & Speed (50rpm) since innovator product (Jardiance) specifies NLT (Q) in 15 min in phosphate buffer 6.8 pH with medium volume of 900ml & speed of 75 rpm.	Firm has submitted that Clinical pharmacology and Biopharmaceutics Reviews report of innovator brand Jardiance tablet have been published in August 2014, in which the Dissolution parameter are 75 rpm, medium phosphate buffer 6.8 pH with medium volume 900ml and (Q) at 15 minutes, However, the latest dissolution method which was published on FDA website, dated 07 Feb 2020 for Empagliflozin tablets is recommended to follow FDA's dissolution guidance 2018 in which dissolution parameters at 50rpm, medium 0.1N HCl with the medium volume of 500ml and (Q) 80% in 30 minutes. We followed the latest FDA recommended dissolution parameters to harmonize the dissolution profile of our product with innovator's brand. ***Firm has referred to FDA dissolution guideline which are applicable when the parameters for dissolution of a specific product are not available in the reviews of the product. As in case of Empagliflozin tablets, data of the innovator product is revealed by the USFDA, so firm has to follow the revealed specifications.*** Firm has now submitted another document wherein they sent an Email to USFDA regarding the adaptation of dissolution method of Empagliflozin and reply of USFDA is reproduced as under; "*We suggest you follow the dissolution method as recommended in the FDA-recommended dissolution database. If you wish to deviate from the posted dissolution method that would be a review that will be evaluated after you submitted your ANDA."* They further submitted revised specification for the dissolution as per innovator product i.e. NLT 80% (Q) in 15 min in phosphate buffer 6.8 pH with medium volume of 900ml & speed of 75 rpm. They further submitted dissolution of all the three trial batches as per new specifications. ***Fee applicable for pre-registration variation is 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.**
- **Registration letter will be issued upon submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

940.	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	ELZA/Plafor 25mg Tablet.

	Composition	Each film coated tablet contains: Empagliflozin ……..……. 25mg.
	Diary No. Date of R& I & fee	Dy. No. 15648 dated 20-09-2017, Fee Rs: 50,000/- dated 16.09.2017 vide deposit slip No. 0275710. (Duplicate dossier verified by R&I section.)
	Pharmacological Group	Antidiabetic (Sodium/glucose co transporter 2 (SGLT2) inhibitor.
	Type of Form	Form 5D.
	Finished product Specifications	Innovator's Specifications.
	Pack size & Demanded Price	Proposed Pack Sizes: 7's, 10's, 14's, 28's, 30's Proposed Price: As per SRO.
	Approval status of product in Reference Regulator Authorities	JARDIANCE® 10mg and 25mg (Empagliflozin film coated tablets), USFDA approved.
	Me-too status	Diampa Tablets 10mg, Getz Pharma, Reg. No. 093074.
	GMP status	Not submitted.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Elza 25mg tablets.		
Manufacturer of API	(Empagliflozin) M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China.		
API Lot No.	Empagliflozin: E-20190920-D02-E06-01.		
Description of Pack (Container closure system)	Light yellow colour, oblong, film coated tablets plain on both sides blistered in Alu-Alu foil packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR001-2/ELZ	TR002-2/ELZ	TR003-2/ELZ
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	01-07.2020	01-07.2020	01-07.2020
No. of Batches	03		
Date of Submission	Dy. No. 9449 dated 26-03-2021.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). 2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. E-20190920-D02-E06-01 Mfg. date 09-11-2019) of the drug substance (Empagliflozin) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China.

<table>
<tr><td></td><td></td><td>Firm has also submitted copy of COA with same batch number and manufacturing date.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of drug substance as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5% RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5% RH for 6 months.
Batches:(20160606, 20161017 & 20161219).</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone.
Valid till 24.08.2023.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Firm has submitted copy of invoice No. HN200424-L dated 01-12-2019 from exporter M/s Beijing Sino Hanson Import & Export Co., Ltd. No.3, Zhonghe road, Fengtai District, Beijing China, for import of 0.4Kg of Empagliflozin (Batch No. E-20190920-D02-E06-01) in name of M/s Tabros Pharma (Pvt). Ltd., Karachi attested by Assistant Director, DRAP, Karachi dated 21-05-2020. Copy of Form 6 attested by Assistant Director, DRAP, Karachi is attached while Form 3 and Form 7 are also provided.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has used same ingredients as that of the innovator product, so compatibility studies with excipients are not required.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TR001-2/ELZ</td><td>1500 Tablets</td><td>15-06.2020</td></tr>
<tr><td>TR002-2/ELZ</td><td>1500 Tablets</td><td>15-06.2020</td></tr>
<tr><td>TR003-2/ELZ</td><td>1500 Tablets</td><td>15-06.2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted comparative dissolution of their applied formulation i.e. Elza (Empagliflozin) 25mg Tablet against Jardiance tablet 25mg, Batch No. 002218, Mfg. date 02-2020 manufactured by Boehringer Ingelheim, Germany in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator:
Sr. No. Observation Reply by the firm</td></tr>
</table>

1.	Latest GMP certificate/last inspection report of the finished product manufacturer conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate No. 53/2022-DRAP (K) dated 15-04-2022 issued on the basis of inspection conducted on 07-04-2022.
2.	Justification shall be submitted for the difference of concentration of the reference solution and test solution in the assay test as the drug substance manufacturer has mentioned 0.02 mg/ml strength while drug product manufacturer has mentioned 0.1mg/ml.	Firm has submitted that they have followed the procedure of drug substance for the determination of assay as similar as manufacturer pertaining to chromatographic condition, wave length, flow rate and mobile phase, only concentration is changed 20mcg to 100 mcg/ml, but we kept same concentration of standard and sample comparable/ alike and validated the method as per ICH guideline, Hence it is acceptable.
3.	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of manufacturing license of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China Valid till 27.11.2027.
4.	Justify dissolution parameters i.e. dissolution limits, dissolution medium, Volume of the medium, RPM and wave length applied for the applied formulation i.e., NLT 80% (Q) in 30 minutes and 0.1N HCL medium, medium volume (500ml) & Speed (50rpm) since innovator product (Jardiance) specifies NLT (Q) in 15 min in phosphate buffer 6.8 pH with medium volume of 900ml & speed of 75 rpm.	Firm has submitted that Clinical pharmacology and Biopharmaceutics Reviews report of innovator brand Jardiance tablet have been published in August 2014, in which the Dissolution parameter are 75 rpm, medium phosphate buffer 6.8 pH with medium volume 900ml and (Q) at 15 minutes, However, the latest dissolution method which was published on FDA website, dated 07 Feb 2020 for Empagliflozin tablets is recommended to follow FDA's dissolution guidance 2018 in which dissolution parameters at 50rpm, medium 0.1N HCl with the medium volume of 500ml and (Q) 80% in 30 minutes. We followed the latest FDA recommended dissolution parameters to harmonize the dissolution profile of our product with innovator's brand. ***Firm has referred to FDA dissolution guideline which are applicable when the parameters for dissolution of a specific product are not available in the reviews of the product. As in case of Empagliflozin tablets, data of the innovator product is revealed by the USFDA, so firm has to follow the revealed specifications.*** Firm has now submitted another document wherein they sent an Email to USFDA regarding the adaptation of dissolution method of Empagliflozin and reply of USFDA is reproduced as under; "*We suggest you follow the dissolution method as recommended in the FDA-recommended dissolution database. If you wish to deviate from the posted dissolution method that would be a review that will be evaluated after you submitted your ANDA."* They further submitted revised specification for the dissolution as per innovator product i.e. NLT 80% (Q) in 15 min in phosphate buffer 6.8 pH with medium volume of 900ml & speed of 75 rpm. They further submitted dissolution of all the three trial batches as per new specifications. ***Fee applicable for pre-registration variation is 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.**
- **Registration letter will be issued upon submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Case No. 04. Deferred cases of Human import drugs applied on form 5F.

Registration Board in its 257th meeting held on 24-25th March, 2016 deliberated that drugs for treatment of chronic ailments and drugs which are in short availability should have priority review process and consideration by the Board to ensure their free availability. The Board decided that drugs for treatment of cancer, viral diseases, thalassemia, immunosuppressant's, vaccine and sera, new molecules / formulations, blood factors and bags will be given priority consideration.
Following applications are placed before the Board for consideration in light of decision of 257th meeting of the registration Board.

941.	Name, address of Applicant / Importer	Biocare Pharmaceutica, 807-Shadman 1, Lahore-Pakistan.
	Details of Drug Sale License of importer	DSL NO. 05-352-0063-032069D. Address: M/s Biocare Pharmaceutica, 807-Shadman 1, District Lahore. Go-down address: 8-C, Street No.3, Near LGS School, Shah Jamal, District Lahore. Valid up to 17-04-2022.
	Name and address of marketing authorization holder (abroad)	Dexa Medica, Jalan Jenderal Bambang Utoyo No. 138,Palembang 30115, Indonesia.
	Name, address of manufacturer(s)	PT Ferron Par Pharmaceuticals, (Dexa Group) - Dexa Medica manufacturer Jababeka Industrial Estate I, Jl. Jababeka VI Blok J-3 Cikarang Bekasi 17520, INDONESIA.
	Name of exporting country	Indonesia.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Detail of certificates attached (CoPP, GMP certificate) **CoPP:** Legalized copy of CoPP (certificate No. RG.01.05.32.321.05.21.2865) dated 26-05-2021 issued by National Agency of Drug and Food Control, Indonesia is submitted. Certificate confirms that the product is actually on the market of the exporting country. Certificate has also mentioned the name of product license holder and manufacturer of the product. Name of the importing country mentioned on the certificate is Pakistan. **GMP:** Legalized copy of GMP certificate No. ST.03.05.33.0331.03.21.000513 dated 08-03-2021 issued by the Indonesian Food and Drug Authority is submitted. Certificate has mentioned that PT Ferron Par Pharmaceuticals, located at Jababeka Industrial Estate I, Jl. Jababeka VI Blok J-3 Cikarang Bekasi 17520, Indonesia manufactures pharmaceutical product under the establishment license No. FP.01.03/IV/0044-e/2020 issued in Jakarta on 26-06-2020 and manufacturing activities are subject to periodic inspections. The standards used for inspection is Indonesian GMP Code which is equivalent to PIC/S and WHO standards. Certificate has validity of 04-03-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of supply and distribution agreement between PT Dexa Medica, Jalan Jenderal Bambang Utoyo No. 138, Palembang 30115, Indonesia (Product license holder) wherein the product license holder Dexa Medica grants an exclusive right to (Biocare Pharmaceutica) for market, sell, distribute the product in the territory using the trade mark including the rights to use the registration documents of the product provided by Dexa for the sole purpose of registering the products in

		the territory.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	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. 2944: dated 31-01-2022.
	Details of fee submitted	PKR 75,000/-: vide slip No. 951976140721 dated 05-01-2022.
	The proposed proprietary name / brand name	Nicardex 10mg/10ml Solution for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml ampoule contains: Nicardipine hydrochloride …… 10mg.
	Pharmaceutical form of applied drug	Solution for Injection.
	Pharmacotherapeutic Group of (API)	Selective Calcium Channel Blockers with mainly Vascular effects. ATC Code: C08C
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	1's and box of 05 ampoules.
	Proposed unit price	PKR 508/ampoule and 2540/box of 05 ampoules.
	The status in reference regulatory authorities	Nicardipine 10 mg/10 ml solution for injection, Laboratoire Aguettant 1 rue Alexander Fleming 69007 LYON FRANCE, MHRA approved.
	For generic drugs (me-too status)	Could not be confirmed.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
	Name, address of drug substance manufacturer	Name: Lusochimica S.p.A. Address: Via Giotto, 9 - 23871 Lomagna (LC), Italy.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification studies, batch analysis (NIC2114, NIC1717 & NIC619) 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)	• 48 months' real time stability data at 25°± 2°C / 60% RH ± 5% RH of 03 batches (2705, 2805 & 2905). • 06 month accelerated stability data 40°C ± 2°C / 70% RH ± 5% RH of 03 batches (2705, 2805 & 2905).
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturer, batch formula, manufacturing process and process control, process validation protocols/report,

		control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (4210382, 5201583 & 5201584), justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against Perdipine injection 10mg/10ml manufactured by Astellas Pharma Japan, Batch No. NY68Y011 by performing quality tests including identification, pH, Osmolarity, Particulate matter, Related substances, Assay, sterility, content of Sorbitol & bacterial endotoxin.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	10ml type I amber glass ampoule.
	Stability study data of drug product, shelf life and storage conditions	• 36-months real time stability data at 30°C ± 2°C / 65% ± 5% RH of 03 batches (K-10290-01-F-PSC-1, K-10290-01-F-PSC-2 & K-10290-01-F-PSC-3). • 06-month accelerated stability data 40°C ± 2°C / 75% ± 5% RH of 03 batches (K-10290-01-F-PSC-1, K-10290-01-F-PSC-2 & K-10290-01-F-PSC-3).
	Therapeutic indications in MHRA.	Nicardipine 10 mg/10 ml solution for injection is indicated for the treatment of acute life-threatening hypertension, particularly in the event of: • Malignant arterial hypertension/Hypertensive encephalopathy. • Aortic dissection, when short acting beta-blocker therapy is not suitable, or in combination with a beta-blocker when beta-blockade alone is not effective. • Severe pre-eclampsia, when other intravenous antihypertensive agents are not recommended or are contra-indicated. • Nicardipine is also indicated for the treatment of post-operative hypertension

Evaluation by PEC:

Sr. No.	Section	Observations	Reply by the firm.
1.	1.1	Submitted fee is in the head of Biological drug division and for biological drug. Clarification shall be submitted.	
2.		Notarized supply and distribution agreement shall be submitted.	
3.	1.4.3	Valid copy of Drug Sale License of the applicant shall be submitted as the submitted DSL is valid up to 17-04-2022.	
4.	1.6.5	Valid copy of GMP certificate of Drug Substance shall be submitted.	
5.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	
6.	3.2.S.4.2	Analytical procedures used for the drug substance by the drug substance manufacturer shall be submitted.	
7.	3.2.S.4.4	• COA of the drug substance manufacturer has loss on drying of NMT 0.5% while the COA of the drug product manufacturer has Loss on drying limit of less than or equal to 1%. Justify.	

	• COAs of the drug product manufacturer has assay test performed by the titration method while the analytical procedure has mentioned USP specification by HPLC method for assay test. Justify.	
8.	3.2.P.8 Accelerated stability data of batch No. K-10290-01-F-PSC-1 & K-10290-01-F-PSC-2 at six-month time point has total impurities out of specifications. Justification shall be submitted.	

Decision of 324th meeting of Registration Board.: Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply by the firm;

Sr. No.	Observations	Reply by the firm.
1.	Submitted fee is in the head of Biological drug division and for biological drug. Clarification shall be submitted.	Firm has submitted that their bank challan receipt clearly shows that they have selected/write registration of new drug for import (not locally manufactured) for Nicardex (Nicardipine HCl) 10mg/10ml and does not select or mention Biological drug division. They further submitted that due to mistake and human error from one of their personnel it was selected Biological drug division and for biological drug head online. They further requested to consider their registration fee for new drug for import (not locally manufactured) head instead of biological head.
2.	Notarized supply and distribution agreement shall be submitted.	Legalized and notarized copy is submitted.
3.	Valid copy of Drug Sale License of the applicant shall be submitted as the submitted DSL is valid up to 17-04-2022.	Copy of license No. 05-352-0063-032069D valid till 17-04-2027 is submitted by the frim.
4.	Valid copy of GMP certificate of Drug Substance shall be submitted.	Copy of GMP certificate No. IT-API/233/H/2022 dated 18-11-2022 is issued in the name of Lusochimica S.p.A. Address: Via Giotto, 9 - 23871 Lomagna by AIFA Italy on the basis of inspection conducted on 03-12-2021.
5.	Specifications of the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
6.	Analytical procedures used for the drug substance by the drug substance manufacturer shall be submitted.	Submitted.
7.	• COA of the drug substance manufacturer has loss on drying of NMT 0.5% while the COA of the drug product manufacturer has Loss on drying limit of less than or equal to 1%. Justify.	Firm has submitted two new COAs of the drug substance from both drug substance manufacturer and drug product manufacturer wherein they have changed the limits of loss on drying i.e. NMT 0.5%.
	• COAs of the drug product manufacturer has assay test performed by the titration method while the analytical procedure has mentioned USP specification by HPLC method for assay test. Justify.	COA from the drug product manufacturer has also assay test on HPLC.
8.	Accelerated stability data of batch No. K-10290-01-F-PSC-1 & K-10290-01-F-PSC-2 at six-month time point has total impurities out	Firm has submitted that results of total impurities during accelerated stability of Nicardipine HCl solution for injection did not meet the specifications. Results of Nicardipine pyridine analogue increased under

	of specifications. Justification shall be submitted.	accelerated conditions. They further referred to International Journal of Pharmaceutics 286 on Evaluation of photo stability of solid state of Nicardipine HCl polymorphs by using Fourier transformed reflection-absorption infrared spectroscopy – effect of grinding on the photo stability of crystal form (Teraoka, et al., 2004) it was proved that Nicardipine HCl in solid state decomposed to a pyridine analog after oxidation of dihydropyridine ring by the light irradiation. Heat could catalyze the degradation process of this degradant. Based on this study, increase of impurity was comparable to the temperature increment. The results of Nicardipine related compound 2 and any unspecified degradation impurity was also increased under accelerated condition. These impurity increment were due to high temperature exposure. They further referred to ICH guidelines: ICH Topic Q1A (R2) Stability testing of new drug substances and product, 2.1.7. Storage conditions "the long term testing should cover a minimum of 12 months" on at least three primary batches at the time of submission and should be constituted for a period of time sufficient to cover the proposed shelf life. Since the shelf life of the product was established based on long term stability study results and the product met the specification during the stability study at proposed storage condition, therefore, we do not rely on accelerated stability study.
Decision: Deferred for following: • **Submission of full fee for the applied product i.e. 75,000/-** • **Justification for out of specification results for the "Total impurities" in Accelerated stability data of batch No. K-10290-01-F-PSC-1 & K-10290-01-F-PSC-2 at six-month time point.**		

Agenda of Evaluator PEC-XV

Registration Application Received On Form 5-F (Imported Product):

942.	**Name, address of Applicant / Importer**	**M/s Grace Pharmaceuticals**
	Details of Drug Sale License of importer	**License No. 152** **Address:** Office no. 503, 5th floor Plot no 42C/2 Lane-08, Bukhari Commercial Phase-6, D.H.A Karachi, Pakistan. **Address of Go down:** NA **Validity:** 21-10-2023 **Status:** License to sell drugs as distributor **Renewal:** Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	**Beijing Beilu Pharmaceutical Co., Ltd.** No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name, address of manufacturer(s)	**Beijing Beilu Pharmaceutical Co., Ltd.** No. 3 Shuiyuan West Road, Miyun District, Beijing, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted notarized (notarized by Beijing Fangyuan Notary Public Office) copy of CoPP certificate (No: 20210127) dated 23-03-2021 issued by Beijing Municipal Medical Product Administration CHINA for Iodixanol injection 50ml. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned.**

		Furthermore the CoPP was valid till 31-10-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beijing Beilu Pharmaceutical Co., Ltd. The letter species that the manufacturer appoints M/s Grace Pharmaceuticals. To register their products in Pakistan. The authorization letter is valid till **30-04-2026**.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 153 : 03-01-2022
	Details of fee submitted	PKR 75,000/-: vide slip no. 5548215985
	The proposed proprietary name / brand name	**Intrapaque 50 mL : 16g I Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Iodixanol …….50ml (50ml:16g I)
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Medical Imaging Drug
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1 VIAL
	Proposed unit price	N/A
	The status in reference regulatory authorities	Visipaque® 320mg Iodine/ml GE Healthcare AS **USFDA APPROVED**
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**GE Healthcare As** Lindesnesveien208, N0-4551 Lindesnes, Norway

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of IODIXANOL Injection instead of iodixanol API. The real time stability data is conducted at 30 ℃±2, RH 65%±5%.
	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 submitted the comparative study on quality of iodixanol injection (50ml:16mg(I) between reference preparation and self-made preparation.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Medium borosilicate glass infusion bottle, strength: 50ml Bottle Pack: Halogenated butyl rubber stopper for injection (chlorinated), strength: 32mm Aluminum-plastic composite cover for infusion bottle, strength: 32mm
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. Accelerated Stability batches: R200101, R200102, R200103 Real Time Stability Batches: R200102 (18 months) R200103 (36 months)

VISIPAQUE

is indicated in for: 1.1 Intra-arterial Procedures Adult and pediatric patients 12 years of age and older

• (270 and 320 mg Iodine/mL) intra-arterial digital subtraction angiography (IA-DSA).

• (320 mg Iodine/mL) angiocardiography (left ventriculography and selective coronary arteriography), peripheral arteriography, visceral arteriography, and cerebral arteriography. Pediatric patients less than 12 years of age

• (320 mg Iodine/mL) angiocardiography, cerebral arteriography, and visceral arteriography. 1.2 Intravenous Procedures Adult and pediatric patients 12 years of age and older

• (270 and 320 mg Iodine/mL) CT imaging of the head and body.

• (270 and 320 mg Iodine/mL) excretory urography.

• (270 mg Iodine/mL) peripheral venography.

• (320 mg Iodine/mL) coronary computed tomography angiography (CCTA) to assist in the diagnostic evaluation of patients with suspected coronary artery disease. Pediatric patients less than 12 years of age

• (270 mg Iodine/mL) CT imaging of the head and body.

• (270 mg Iodine/mL) excretory urography.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued by relevant regulatory	

	authority in the country of origin and name of exporting country, since the submitted CoPP is invalid.	
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 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".
3.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
4.	**3.2.S.4.3**	Submit batch analysis report of drug substance 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. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".*
5.	**3.2.S.5**	Submit COA of reference standards in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, however for non-pharmacopeial Drug Substance, a secondary reference standard provided by the Drug Substance manufacturer is acceptable. COA of primary / secondary reference standard including source and lot number shall be provided".*
6.	**3.2.S.6**	Submit details of container closure system of drug substance in section 3.2.S.6 as per the guidance document approved by Registration Board which specifies that "*Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component. Other information on the container closure system(s) (e.g. suitability studies) may be submitted".*
7.	**3.2.S.7**	Submit data in section 3.2.S.7 as per the guidance document approved by Registration Board which specifies that "The protocols used and the results of the accelerated and long-term stability studies shall be summarized. Proposed storage conditions / statement and re-test period (or shelf-life, as appropriate) shall also be submitted". Since you have submitted the compatibility results of Iodixanol with excipient.
8.	**3.2.P.2.2.1**	Submit details regarding batch number, manufacturing and expiry date of your as well as the comparator product used in pharmaceutical equivalence studies.
9.	**3.2.P.5.3**	Submit data of verification of assay procedure of drug product in section 3.2.P.5.3 as per the guidance document approved by Registration Board which specifies that "*All the officially recognized compendial methods for assay, dissolution and impurities (as applicable) are required to be verified and verification shall include a demonstration of specificity, repeatability (method precision) and accuracy".*

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

943.	**Name, address of Applicant / Importer**	**M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd floor plaza 60, commercial block K, phase 1 DHA, distt. Lahore **Address of Godown:** NA **Validity:** 24-02-2023.

		Status: License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Name, address of manufacturer(s)	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 20210368) dated 08-2021 issued by CCPIT for compound alpha ketoacid tablet. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 01-08-2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Hebei tiancheng pharmaceutical Co. Ltd. The letter species that the manufacturer appoints **M/s AMB HK ENTERPRISES Pvt Ltd, Pakistan** to register their products in Pakistan. The authorization letter is valid till 08-2026.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.3529 dated 07-02-2022
	Details of fee submitted	PKR 150,030/-: 02-11-2021
	The proposed proprietary name / brand name	Ketogen tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Compound α- Ketoacid …….0.63g
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	amino acid , including combination with polypeptide
	Reference to Finished product specifications	In house
	Proposed Pack size	20 tablets/blister, 5 blisters/box
	Proposed unit price	Rs. 3450/- box
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	Not confirmed

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Hebei tiancheng pharmaceutical Co. Ltd. No. 18, Jinguang street, economic and technological development zone, cangzhou city, Hebei province, china.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 30 ℃±2. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 2 batches is for 12 months while the stability study data for 3rd batch is for 9 months only.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

944.	**Name, address of Applicant / Importer**	**M/s. Hospital Supply Corporation**
	Details of Drug Sale License of importer	**License No:0013** **Address:** 42, Darul Aman Housing Society, Karachi **Address of Godown:** 46-E-2, Block-6, PECHS, Karachi **Validity:** 29-06-2022

		Status: License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey
	Name, address of manufacturer(s)	Mefar Ilac San A.S. Ramazanoglu Mahalles Ensar Caddesi No.2 Istanbul Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No.2021/3007) dated 01-10-2021 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 01-10-2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey. The letter species that the manufacturer appoints **M/s. Hospital Supply Corporation** to register their products in Pakistan. The authorization letter is valid till 31-12-2024.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.795 : 10-01-2022
	Details of fee submitted	PKR 150,030/-: 26-10-2021
	The proposed proprietary name / brand name	Biemexol 350mgI/ml vial (50ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	X-Ray Contrast Media
	Reference to Finished product specifications	In-house specification
	Proposed Pack size	50ml vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved.
	For generic drugs (me-too status)	Monopague 350mg/ml Injection (063945) of M/s. Graton Pharma, Karachi.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejian Province** **Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China**
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25℃±2, 60% RH±5%. The stability study data is till 36 months. **Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejian Province** Batch no. H18920080501, H18920080502, H18920080503 **Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China** Batch no. C006-0802003, C006-0802004, C006-0802005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of 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 established against Omnipaque 350mgI/ML Vial (Batch no. 14778967)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colorless type I Glass vial (50ml), bromobutyl closure, blue tear off cap
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 24 month has submitted.

INDICATIONS AND USAGE:
OMNIPAQUE (iohexol) injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. OMNIPAQUE oral solution is indicated for oral use only in conjunction with OMNIPAQUE injection administered intravenously for computed tomography (CT) of the abdomen.

DOSAGE AND ADMINISTRATION:

The concentration and volume required will depend on the indication, size and condition of the patient, and the equipment and imaging technique used. For CT of the head and body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE. See full prescribing information for complete dosing information.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit valid drug sale license of importer Hospital supply corporation ,since the submitted DSL was expired on 29-06-2022.	
2.	According to the composition table associated with CoPP of drug product,API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material comply EP specification ,so clarification is required in this regard.	
3.	**3.2.S.4**	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".
4.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer.
5.	**3.2.S.7**	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.
6.	**3.2.P.2.2.1**	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.
7.	**3.2.P.5.1**	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia. Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.
8.	**3.2.P.8**	Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8. Submit the complete data of long term stability studies performed at zone IV-a conditions, since you have claimed shelf life of 36months and provide the data of 24 months.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

945.	**Name, address of Applicant / Importer**	**M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.**
	Details of Drug Sale License of importer	**License No:041** **Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.** **Address of Go down:** Same as above **Validity:** 19-11-2022 **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s. Anhui Chengshi Pharmaceuticals Co. Ltd. No. 5068 Huaishang Road, Bengbu, Anhui Province, China
	Name, address of manufacturer(s)	M/s. Anhui Chengshi Pharmaceuticals Co. Ltd. No. 5068 Huaishang Road, Bengbu, Anhui Province, China

	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized of CoPP certificate (No. nil) dated 29-07-2021 without the name of issuing authority. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid for 5 years.** GMP certificate issued by China Food and Drug Administration to M/s. Anhui Chengshi Pharmaceuticals Co. Ltd. No. 5068 Huaishang Road, Bengbu, Anhui Province, China dated 08-03-2021 and valid till 08-03-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of agency agreement between Anhui Chengshi Pharmaceuticals Co. Ltd. and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter species that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products including atropine sulphate 1mg/1ml in Pakistan. The agreement letter will be terminated if the registration of the product is failed until 1 july,2022 and the term of agreement will be 5 years from 1 july,2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.667 dated 07-01-2022
	Details of fee submitted	PKR 100,030/-: dated 07-04-2021 and differential fee of Rs.50,000/- vide slip no. 0114822752 dated 07th June,2021 submitted
	The proposed proprietary name / brand name	Atropine Sulphate Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule (1ml) contains: Atropine Sulphate….1mg
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	cholinergic muscarinic antagonist
	Reference to Finished product specifications	BP specification
	Proposed Pack size	1mg/1ml Injection
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**TGA approved**

	For generic drugs (me-too status)	Atrosol injection 1mg/ml of M/s. Indus Pharma (Pvt.) Ltd. Korangi Industrial Area Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Henan Purui Pharmaceutical Co. Ltd. Yezhuangqiao Village, Xinhua County, Zhoukou City, Henan Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 36 months. Batch no. 20040301,20040302,20040303
	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	submitted. Pharmaceutical Equivalence established against the products of M/s.Aspen Pharma Trading Limited, M/s. Xinxiang Changle Pharmaceutical Co. Ltd., M/s. Zhejiang Xianju Pharmaceutical Co. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass ampoule low borosilicate glass volume of 1.5ml.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 24 month has submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.4.1	Provide clarification, whether the applied product (drug product) is intended for sale in domestic market or both for domestic and export market.
2.	3.2.P.1	Justify for using 8.5 mg /ml sodium chloride comparing the composition of innovator brand in which 9mg/ml sodium chloride is used. Further, the composition of innovator brand includes sodium hydroxide and/or sulfuric acid for pH adjustment, while you have not been using any of the pH adjustment agent in the composition of applied product.
3.	3.2.P.3.1	Can you please co-relate the manufacturing procedure given in section 3.2.P.3 with the composition of applied injection because neither the procedure includes any of

		the active ingredient or excipients nor the pH measurement/adjustment is the part of solution preparation.
4.	3.2.P.3.5	Justify for keeping the pH limit of injection between 3.0-4.0 while the process validation ,since the recommended pH limit as per BP is 2.8-4.5.
5.	3.2.P.5.3	Justify for not complying the BP monograph while performing the analytical method verification studies of drug product.
6.	3.2.P.6	Submit COA of reference/working standard used in the analysis of drug product.
7.	3.2.P.8	Please clarify the designation of signing authority ,who correct the storage condition on the stability data sheet of Batch no. W170419 along with documented evidence.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

946.	Name, address of Applicant / Importer	M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.
	Details of Drug Sale License of importer	License No:041 Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi. Address of Go down: Same as above Validity: 19-11-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name, address of manufacturer(s)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized of CoPP certificate (No. 2105062) dated 27-05-2021 by the issuing authority Yiyuan Market Supervision and Administration of P.R. China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 26-05-2023.** GMP certificate issued by China Food and Drug Administration to M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. dated 13-06-2018 and valid till 12-06-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted agent & distributor agreement between M/s. Qingdao JidaBarr International Trade Co., Ltd., No.-2, B-1-4, Heilongjiang South Road, Qingdao City, China **(Exporter), M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.** and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter specifies that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☒ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.1739 dated 19-01-2022
	Details of fee submitted	PKR 150,030/-: DATED 03-01-2022
	The proposed proprietary name / brand name	BenzylPenicillin Sodium 500,000 IU Injection (0.5 Mega)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Benzylpenicillin Sodium eq. to Benzyl penicillin…0.5 Mega
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Beta-lactamase sensitive penicillins
	Reference to Finished product specifications	BP specification
	Proposed Pack size	10 vials/box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not confirmed
	For generic drugs (me-too status)	Not confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No.88 Yangzi Road Economic & Technological Development Zone Shijiazhuang City Hebei Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 24 months. Batch no. 891805901, 891805901, 891805901 Claimed 48 months but provided data of 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	submitted. Pharmaceutical Equivalence established against the product of M/s. Shandong Lukang Pharmaceuticals Co. Ltd., China
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	7ml Type-II glass vial rubber stopper flip off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 36 months has submitted.

Evaluation by PEC:

S.no.	Observations/Deficiencies/ Short-comings
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

947.	**Name, address of Applicant / Importer**	**M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.**
	Details of Drug Sale License of importer	**License No:041** **Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.** **Address of Go down:** Same as above **Validity:** 19-11-2022 **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name, address of manufacturer(s)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized of CoPP certificate (No. 2105062) dated 27-05-2021 by the issuing authority Yiyuan Market Supervision and Administration of P.R. China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 26-05-2023.** GMP certificate issued by China Food and Drug Administration to M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. dated 13-06-2018 and valid till 12-06-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted agent & distributor agreement between M/s. Qingdao JidaBarr International Trade Co., Ltd., No.-2, B-1-4, Heilongjiang South Road, Qingdao City, China **(Exporter), M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.** and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter specifies that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☒ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.1740 dated 19-01-2022
	Details of fee submitted	PKR 150,030/-: DATED 03-01-2022
	The proposed proprietary name / brand name	BenzylPenicillin Sodium for injection 1 mega
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Benzylpenicillin Sodium eq. to Benzyl penicillin…1 mega
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Beta-lactamase sensitive penicillin
	Reference to Finished product specifications	BP specification
	Proposed Pack size	10 vials/box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Benzyl penicillin sodium injection 1000,000 IU OF IMPORTER United international (Reg.no. 043024)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No.88 Yangzi Road Economic & Technological Development Zone Shijiazhuang City Hebei Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25℃±2, 60% RH±5%. The stability study data is till 24 months. Batch no. 891805901, 891805901, 891805901 Claimed 48

		months but provided data of 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	submitted. Pharmaceutical Equivalence established against the product of M/s. Shandong Lukang Pharmaceuticals Co. Ltd., China Benzyl penicillin Sodium for Injection (1mega)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	7ml Type-II glass vial rubber stopper flip off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 36 months has submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit evidence of approval status of applied formulation in the approved reference regulatory agencies in the same strength i.e. 1,000,000 IU.	
2.	Clarify the strength of applied formulation, since you have applied for benzyl penicillin sodium injection 1,000,000 IU while the CoPP is of benzyl penicillin sodium for injection 1 mega. Please submit the conversion/equivalent calculation from 1,000,000 IU to 1 mega.	
3.	**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". Analytical procedure of drug substance by drug substance manufacturer is different from the procedure specified in EP monogragh,Justify how the raw material comply EP specification as claimed in the batch analysis report.
4.	**3.2.S.4.3**	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer.
5.	**3.2.P.1**	According to the composition of finished product given in section 3.2.P.1 599mg equivalent to benzyl penicillin 1mega powder for injection is filled per vial while the reference product approved in MHRA claimed that Each vial contains Benzylpenicillin sodium 600 mg (1 mega unit). Comparing the label claim/ strength justify how the applied product is similar to the reference product.
6.	**3.2.P.1 (c)**	Provide details of type and quantity of diluents used for reconstitution for of applied product.
7.	**3.2.P.2.2.1**	According to the pharmaceutical equivalence report content of penicillin has calculated while the BP recommends quantification of benzypenicillin content, justification is required in this regard.
8.	**3.2.P.5.1**	Clarify the content of penicillin in term of benzyl penicillin as recommended by BP monograph.

9.	**3.2.P.5.3**	Assay procedure followed while performing the validation studies is different from the recommended assay procedure given in BP monograph of benzypenicillin sodium injection, justification is required in this regard.
10.	**3.2.P.8**	Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

948.	**Name, address of Applicant / Importer**	**Biocare Pharmaceutica.** **Address:- 807 Shadman-1, Lahore**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-032069D **Address: 807 Shadman-1, District Lahore**. **Address of Godown:** First floor B-C, Street No. 3, Near LGS School, Shah Jamal District Lahore. **Validity:** 17-04-2022. **Status:** License to sell drugs as distributor **Renewed/New DSL:** Drug sales License is renewed. New Drug Sales License is attached for DRAP reference. (New License No. 05-352-0063-032069D), **Validity**: - 17.04.2027.
	Name and address of marketing authorization holder (abroad)	**License Holder/Supplier:** PT Pratapa Nirmala (Fahrenheit) **Address:** Jl. Industri VI, Tangerang 15135, Indonesia **Phone:** +62-21-5901876 / 77 E-mail: john@fahrenheit.co.id
	Name, address of manufacturer(s)	**Manufactured by: -** PT Pratapa Nirmala (Fahrenheit) **Address:** Jl. Industri VI, Tangerang 15135, Indonesia Phone: +62-21-5901876 / 77, Fax: +62-21-5901984 E-mail: john@fahrenheit.co.id
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP with certificate No. RG.01.05.32.321.01.21.2397, dated January 21, 2021 issued by National Agency of Drug and Food Control, Indonesia. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. The name of importing country on CoPP is mentioned as Pakistan. **Embassy Attested/Legalized GMP is also attached. GMP Validity is December, 20, 2023.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of legalized distribution agreement signed by both parties Biocare Pharmaceutica & PT Pratapa Nirmala (Fahrenheit). Agreement clearly mention Aboard License Holder PT Pratapa Nirmala (Fahrenheit) (Indonesia) appoints M/s Biocare Pharmaceutica to register/market/sell/Distribute their product Farpresin (Vasopressin)20 IU/ml. Inj.in Pakistan. **Agreement validity is 5 years with additional 5-years renewal clause.**
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.no. 2945 dated 31-01-2022
	Details of fee submitted	PKR 150,000 /-: Slip # 6700351198, Date:- 05/01/2022
	The proposed proprietary name / brand name	FARPRESIN
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	20 IU/mL. Each 1 mL contains Vasopressin.
	Pharmaceutical form of applied drug	Farpresin (Vasopressin) is a clear, colorless solution for intravenous administration available as 20 units/mL in 1-mL vial
	Pharmacotherapeutic Group of (API)	Vasopressin and analogues WHO ATC H01BA01
	Reference to Finished product specifications	USP43
	Proposed Pack size	5 Vials per Pack (Box 5 Vials)
	Proposed unit price	Rs 900/Vial. Rs. 4500 for 5 Vials Box
	The status in reference regulatory authorities	Vasopressin 20 IU/ml is US FDA & Health Canada approved drug. In USA it is manufacture/marketed by American Regent, Inc. & in Canada it is manufacture/marketed by Fresenius Kabi Canada.
	For generic drugs (me-too status)	M/s. Platinum Pharmaceuticals, Brand: - Vasopressin Injection, Strength: - 20units/ml, Composition: - Vasopressin, Reg. No. 015590, Dosage Form: - Injectable Solution in Vial for Intravenous (IV) Use
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Name: BCN Peptides S.A. Address: Pol. Ind. Els Vinyets-Els Fogars, II 08777 Sant Quinti de Mediona Barcelona, Spain
	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 (VP0401, VP0501, VP0701) of API at accelerated (25 °C ± 2° C 60% ± 5%) as well as real time long term (5 °C ± 2° C) conditions. The 6 months accelerated study is complete for 3 batches. The real time 3 batches stability

		data are conducted till 36 months. [Reference:- Specifications according to the previous Vasopressin monograph USP31-NF26 in accelerated & long term API stability testing].
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference original brand Vasostrict (Vasopressin) 20 unit/ml Solution for Injection manufactured by (Par Pharmaceutical Chestnut Ridge, NY 10977), US., Lot: 36748 Exp Date: 12-2022. Based upon results comparison and details provided, Pharmaceutical equivalence is established between FARPRESIN and reference brand VASOSTRICT.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Farpresin (Vasopressin) 20 unit /ml Inj. is filled into glass type 1 vial-1ml with Bromobutyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	24 months real time stability data (Long Term) at 30°C ± 2°C / 75% ± 5%RH of 03 batches (Zone IVB) is Submitted. 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches is submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Please provide legalized documents which established the link between Fahrenhite and PT. Partapa Nirmala,since all your legalized documents including CoPP, Free Sale certificate and GMP inspection report of Manufacturer Abroad revealed that the name of manufacturer is PT. Partapa Nirmala.	
2.	**1.3.4**	Justify for not having segregated manufacturing facility for preparation of hormones, since the Manufacturer Abroad have manufactured the vasopressin injection in non-betalactum Small volume injection section.
3.	**3.2.S.4.2**	Justify for not performing the identification test via Mass Spectral Analysis of drug substance by drug product manufacturer since the USP recommends identification test both via HPLC and Mass spectral analysis.
4.	**3.2.S.4.4**	Batch analysis report of batch no. VP-1803 by drug product manufacturer evident that result of bacterial endotoxin test was out of specification despite of keeping the acceptance limit <100IU/mg, while Limits of BET test recommends by the official Pharmacoepias and the acceptance limit adopted by the drug substance manufacturer (BCN Peptides) is <10IU/mg. Justify for accepting the batch of drug substance which is failed to pass the bacterial endotoxin test, further provide the Pharmaceopial/international literature which recommends the acceptance limit <100IU/mg.
5.	**3.2.S.7**	• Justify for not performing the test of water content, test for acetic acid in peptides, microbial enumeration test and test for specified microorganism while performing the stability study of drug substance despite these test are included in the USP monograph of vasopressin. • Justify for adapting the acceptance limit of assay NLT 300IU/mg in the stability studies comparing the acceptance criteria recommended in USP monograph i.e. NLT 95.0% and NMT 105.0% of vasopressin (C46H65N15O12S2), calculated on the anhydrous, acetic acid-free basis.

6.	**3.2.P.1**	• Please provide calculation along with equivalent factor to established link between 20 units /ml and 0.0667mg/ml along with evidence of reference product approved in Reference regulatory Agencies with the same composition. • Justify for using different excipient from that of 1ml composition of innovator product approved in USFDA, since 1ml of injection of innovator brand contains sodium acetate buffer and water for injection without any preservative.
7.	**3.2.P.2.2.3**	Justify for not performing the sterility test, Bacterial endotoxin test and particulate matter in injection test while performing the pharmaceutical equivalence against the innovator/reference product.
8.	**3.2.P.5.2**	Assay procedure specified in section 3.2.P.5.2 is not in accordance with USP monograph of vasopressin injection, justify for using different assay method from that recommended in USP.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

949.	**Name, address of** Applicant / **Importer**	**M/s. M&M Pharma Javaid Plaza, Opposite Pepsi Gate.2, Gurumangat Road, Gulberg-II District Lahore**
	Details of Drug Sale License of importer	**License No:0000009412** **Address: Javaid Plaza, Opposite Pepsi Gate.2, Gurumangat Road, Gulberg-II District Lahore** **Address of Go down:** Same as above **Validity:** 19-10-2022 **Status:** License to sell drugs as distributor **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s. HLL Lifecare Limited (A. Govt. of India Enterprise) survey no. 76/3+7+8+9,75/1+2+3,59/1&2 Kanagala-591225, Dist: Belagavi. Karnataka India
	Name, address of manufacturer(s)	M/s. HLL Lifecare Limited (A. Govt. of India Enterprise) survey no. 76/3+7+8+9,75/1+2+3,59/1&2 Kanagala-591225, Dist: Belagavi. Karnataka India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP certificate (GSC No. DD0990000017860) dated 22-11-2019 by the issuing authority Drug Control Department Karnataka India. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 25-06-2022.** Firm submitted WHO public inspection report related to the WHO product no. RH065 Levonorgestrel 1.5 mg Tablet.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization in the name of M/s. M&M Pharma Javaid Plaza, Opposite Pepsi Gate.2, Gurumangat Road, Gulberg-II District Lahore from M/s. HLL Life care Limited, Karnataka ,India to register/market the product Oral Contraceptive pills & Emergency Contraceptive pills with Ministry of Health Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.2812 dated 28-01-2022
	Details of fee submitted	PKR 100,030/-: DATED 09-01-2020 (Differential fee required)
	The proposed proprietary name / brand name	UNIPILL Tablet 1.5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levonorgestrel…..1.5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Progestogens
	Reference to Finished product specifications	BP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Not confirmed
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Qinhuangdao Zizhu Pharmaceutical Co. Ltd. No.10 Longhai Road, Economic and Technological Development Zone, Qinhuangdao City, Hebei Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, 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 product instead of stability data of drug substance.
	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	submitted. Pharmaceutical Equivalence established against the comparator product of Plan B One-Step (Levonorgestrel) Tablet 1.5mg of M/s. Gedeon Richter Ltd., Budapest , Hungary and comparative dissolution

		studies has also conduct against the same comparator product.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Alu-PVDC COATED PVC foil blisters
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 60 months has submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit original ,valid and legalized CoPP of drug product, since you have submitted the copy of CoPP.	
2.	Submit valid Drug Sale License of ,since the submitted DSL was expired on 19-10-2022.	
3.	**3.2.S.4.2**	Justify for performance of assay using UV Spectrophotometer while the EP recommends Potentiometric titration method for assay testing of drug substance.
4.	**3.2.S.7**	Submit stability data of drug substance performed at accelerated and long term stability conditions till the claimed shelf life/re-test period, since the submitted data in section 3.2.S.7 is of drug product instead of drug substance.
5.	**3.2.P.1**	According to the WHO assessment report of applied product lactose monohydrate is of bovine origin. Please submit the details related to the originating source of lactose monohydrate .
6.	**3.2.P.5.2**	Justify for keeping the detection wavelength 243nm in the chromatographic condition of dissolution testing of drug product comparing the detection wavelength recommended in the BP monograph of levonorgestrel tablet i.e.220nm.
7.	**3.2.P.8**	Justify the variation observed in acceptance criteria of dissolution while performing the stability data of drug product. As evident from the submitted stability data, at certain time points the acceptance criteria of dissolution has set at **Qvalue-75% of the active substance release in 60 min** while at other time points dissolution criteria has kept at **NLT 80% in 30minutes**.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

950.	**Name, address of Applicant / Importer**	**M/s AGP Limited. B-23, S.I.T.E. Karachi**
	Details of Drug Sale License of importer	**License No: 132** **Address:** 1st Floor, Shafi Court, Civil Lines, Merewether Road, Karachi, Pakistan. **Address of Godown:** Plot No.44, Sector27, Korangi Industrial Area, Karachi **Validity:** 22.12.2022. **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s MEDA Pharma GmbH & CO., KG, Benzstrasse 1, 61352 Bad, Homburg, Germany
	Name, address of manufacturer(s)	M/s MEDA Manufacturing Avenue J. F. Kennedy 33700 Mérignac France
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No. COTJA) issued on 01-10-2019 issued by German authority. The Applied product is available for free sale in exporting country i.e, Germany. **GMP:** Firm has submitted legalized copy of Eudra GMP certificate no. 2019/HPF/FR/317 valid till 19-09-2022.
	Details of letter of authorization / sole	Copy of Letter of Authorization between M/s MEDA

	agency agreement	Pharma GmbH & CO., KG, Benzstrasse 1, 61352 Bad, Homburg, Germany and **M/s AGP Limited. B-23, S.I.T.E. Karachi** to register, Import & market authorisation of the applied product. The authorization letter is valid till 01-01-2022
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	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 1450 dated 17-01-2022
	Details of fee submitted	Rs.100,000/- dated 04-12-2020
	The proposed proprietary name / brand name	**Elidel 1% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Cream Contains: Pimecrolimus ……10mg
	Pharmaceutical form of applied drug	Topical Cream
	Pharmacotherapeutic Group of (API)	D11AH02 Other dermatological preparations. Agents for dermatitis, excluding corticosteroids
	Reference to Finished product specifications	In-house specification.
	Proposed Pack size	--
	Proposed unit price	--
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	NA
	Name, address of drug substance manufacturer	M/s Lek Pharmaceuticals d.d. Kolodvorska 27 1234 Mengeš Slovenia
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated (25ºC ± 2ºC/60%± 5% RH) as well as real time conditions (5ºC ± 3ºC).
	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 applicable since applied product is innovator.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Packaged in aluminium tubes sealed with a membrane (aluminium seal). The tubes are closed with a polypropylene screw cap which has a built-in point to pierce the aluminium seal.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 3 batches for different pack sizes is as under: 5gm tube = 12months 10g, 15g, 30g, 60g and 100g tubes = 18 months

Evaluation by PEC:

Section	Observations	Firm's response
1.3	• Copy of valid DSL shall be submitted. • Notarized copy of valid letter of authorization shall be shall be submitted.	• Valid DSL is submitted by the firm with the validity of 21-09-2023. • Firm replied that they have requested for the valid letter of authorization from our Principal Manufacturer and will provide as received.
1.5.4	Submit demand pack size and price for the applied formulation.	Firm demanded the pack size 15g and 10g with the proposed price of Rs.2000/- and 1500/- respectively.
3.2.P.5.2	Test for efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter <51>, has not been included in the finished product specifications. You are advised to submit justification in this regard.	Firm replied that the required data for efficacy of preservative provided in the dossier. According to the ICH Q1(R2) guidelines it is mentioned under point 2.2.5 that the specification for the preservative content should be included in specification 3.2. P.5.2. This requirement is fulfilled in module 3 section 3.2. P.5.2 (J. Benzyl Alcohol, identification and assay by GC). Furthermore, the ICH guidelines request that the "preservative effectiveness demonstrated during drug development in its final formulations" [ICH guidelines Q1 (R2) 2.2.5].
3.2.P.5.3	Analytical method validation studies for the "Assay" test of drug product shall be submitted.	Firm submitted the analytical method validation studies report for assay of drug product .
3.2.P.8.3	Clarification shall be submitted for the claimed shelf life against the applied pack size since submitted stability data declares different shelf life for different pack sizes.	Firm replied that the product will be imported in Pakistan in the pack size of 10g & 15g. The shelf life of 10g & 15g is 18 months. Therefore they requested to approved the pack size of 10g & 15g with the shelf life of 18months.

Decision: Approved as per policy of inspection of manufacturer abroad. Further, Registration Board decided to grant shelf life of shelf life of 18 months only for the pack size of 10g & 15g.

951.	**Name, address of Applicant / Importer**	**M/s. VIZ Remedies Pakistan LLP**
	Details of Drug Sale License of importer	**License No. 1174**

		Address: Suit No.26 4th Floor Kehkashan Mall, Tariq Road. Block-2 PECHS Karachi **Address of Go down:** NA **Validity:** 13-02-2022 **Status:** License to sell drugs as distributor **Renewal:** Firm has submitted for renewal
	Name and address of marketing authorization holder (abroad)	**Xi'an Wanlong Pharmaceutical Co. Ltd.** No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name, address of manufacturer(s)	**Xi'an Wanlong Pharmaceutical Co. Ltd.** No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP certificate (No: 20200029) dated 16-06-2020 issued by Shaanxi Provincial Drug Administration. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. **The name of importing country on CoPP is mentioned. Furthermore, the CoPP was valid till 15-06-2022.** Copy of GMP certificate of M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. is submitted which was valid till 22-09-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of Exclusive Marketing Agreement between M/s. VIZ Remedies Pakistan LLP and M/s. Xi'an Wanlong Pharmaceutical Co. Ltd. The letter specifies that the manufacturer appoints M/s. VIZ Remedies Pakistan LLP. Is their exclusive agent in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24063 : dated 01-09-2021
	Details of fee submitted	PKR 100,000/-: dated 18-01-2021 (Differential fee of Rs. 50,000/- is to be submitted by the firm)
	The proposed proprietary name / brand name	**Tirofiban Hydrochloride Injection 5mg/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100mL contains: Tirofiban Hydrochloride (calculated based on Tirofiban)5mg
	Pharmaceutical form of applied drug	Injection.
	Pharmacotherapeutic Group of (API)	Anti-Platelet
	Reference to Finished product specifications	Innovator's Specification

	Proposed Pack size	1x100ml neutral borosilicate glass infusion bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (AGGRASTAT Injection)
	For generic drugs (me-too status)	Not confirmed in the applied volume i.e.100ml
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Xi'an Wanlong Pharmaceutical Co. Ltd.** No.2 Yongan Road, Yangling Agricultural Hi-tech Industrial Demonstration Zone Shaanxi China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Drug substance monograph is present in USP.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 three batches of Tirofiban hydrochloride Injection instead of Tirofiban hydrochloride API.
	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 study has been performed against the innovator product AGGRASTAT Injection (Batch no. C856260) which includes quality test (Appearance, pH , Assay, Citric Acid and sodium citrate content, sodium chloride content and related substance test.)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	100ml- neutral borosilicate glass Infusion bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 following batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. **B171001,B171002,B171003**

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.3**	Submit valid original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and GMP certificate of the Manufacturer issued

		by relevant regulatory authority in the country of origin and name of exporting country, since the submitted documents are invalid.
2.	**1.4**	Submit valid drug sale license of **VIZ Remedies Pakistan LLP ,**since you have submitted the expired DSL.
3.	**3.2.S.7**	Submit stability data of three batches of drug substance performed at long term stability conditions till the claimed re-test date since you have submitted the data of only 12 months.
4.	**3.2.P.3**	Justify the use of activated carbon in the manufacturing procedure of sterile preparation to remove the bacterial endotoxin in the light of guidance documents of reference agencies.
5.	**3.2.P.5.1**	Justify how the labelled amount of tirofiban will be quantify, since the assay method given in section 3.2.P.5.2 calculate the quantity of tirofiban hydrochloride instead of labelled quantity of tirofiban without the salt factor.
6.	**3.2.P.5.4**	Justify for using the excipient sodium chloride in the product name along with tirofiban hydrochloride.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Withdrawal of Registration Applications by M/s. Grace Pharmaceuticals:

M/s. Grace Pharmaceuticals in its letter dated 2nd February ,2023 informed that they would like to withdraw following registration application of their imported products:

Sr.no.	Name and Address of Manufacturer & Importer	Brand name along with composition	Details of Registration Application
1.	M/s Grace Pharma. 503, 5th Floor, Plot 42C/2, Lane 08, Bukhari Commercial, DHA Phase 6 Karachi **Marketing Authorization Holder of Manufacturer Abroad:** M/s Beijing Beilu Pharmaceutical Co., Ltd.No 3 Shuiyuan West Road, Miyun District, Beijing, China	Monopaque Injection Each 100ml Contains: Iohexol 100ml:35g(I)	Form-5F Dy.No 32572 dated 30-11-2021 Rs.75,000/- dated 29-10-2021
2.	M/s Grace Pharma. 503, 5th Floor, Plot 42C/2, Lane 08, Bukhari Commercial, DHA Phase 6 Karachi **Marketing Authorization Holder of Manufacturer Abroad:** M/s Beijing Beilu Pharmaceutical Co., Ltd.No 3 Shuiyuan West Road, Miyun District, Beijing, China	Each 50ml Contains: Iohexol 50ml:17.5g(I)	Form-5F Dy.No 32565 dated 13-12-2021 Rs.75,000/- dated 29-10-2021

Decision: Registration Board acceded the request of withdrawal of firm and declared the above registration applications as disposed off.

Registration Application Received On Form 5-F (Local Manufacturing)

952.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2946 date of submission: 31-01-2022
	Details of fee submitted	PKR 75,000/-: dated 18/01/2022
	The proposed proprietary name / brand name	Segana XR 5mg/2.5mg/1000mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Empagliflozin….5mg Linagliptin…….2.5mg Metformin Hcl……..1000mg (as extended release)
	Pharmaceutical form of applied drug	Tablet, Extended Release
	Pharmacotherapeutic Group of (API)	**Metformin HCL** biguanide class of antidiabetics **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors.
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR Tablet of BOEHRINGER INGELHEIM (FDA approved)
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-01-2024.
	Name and address of API manufacturer.	<u>EMPAGLIFLOZIN:</u> • Fuxin long rui pharmaceutical Co., Ltd. <u>METFORMIN HCL:</u> • Aarti drugs limited <u>LINAGLIPTIN:</u> • M/s. Venkata Narayana Active Ingredients
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 66 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **EMPAGLIFLOZIN** Batches: (20160606, 20161017, 20161219) **METFORMIN HCL** Batches: (MEF/1410027 MEF/1410028, MEF/1410029) **LINAGLIPTIN** batches: (LNG20131220 LNG20141220, LNG20151220)
	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	The Firm has performed pharmaceutical equivalence profile of their developed formulation Segana XR 5mg/2.5mg/1000mg tablet (B #ST21007) with innovator product Trijardy XR Tablets (B # 3185610) of M/s Boehringer Ingelheim Pharma, USA. The results showed that release profile of both test and comparator products were comparable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API		EMPAGLIFLOZIN: • Manufacturer: FUXIN LONG RUI PHARMACEUTICAL Co., Ltd. METFORMIN HCL: • Manufacturer: AARTI DRUGS LIMITED LINAGLIPTIN: • Manufacturer: M/s. Venkata Narayana Active Ingredients
API Lot No.		(Empagliflozin): E-20190920-D02-E06-01 (Metformin HCL): MEF/10030953

	(Linagliptin): LG0131220		
Description of Pack (Container closure system)	HDPE bottles (30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 36 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,18, 24 & 36 (Months)		
Batch No.	ST21J007	ST21J008	ST21J009
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	28-09-2021	28-09-2021	29-09-2021
No. of Batches	03		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**EMPAGLIFLOZIN:** Copy of GMP issued by Food & drug authority china valid till 23/08/2023. **METFORMIN HCL:** Copy of GMP certificate No. 20031933 issued by Food & drug Control Administration valid till 19/03/2023. **LINAGLIPTIN:** Copy of GMP certificate issued by drug Control Administration Andhra Pradesh valid till 07/12/2024.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of **EMPAGLIFLOZIN** (1.5 Kg, Invoice # HN19120501-H) and attested copy of form 6 (I&E) DRAP, Islamabad dated 10-01-2020. The firm has submitted copy of invoice for the import of **METFORMIN HCL** (1000 Kg, Invoice # EXP/302/20-21) and attested copy of form 6 (I&E) DRAP, Islamabad dated 05-08-2020. The firm has submitted copy of invoice for the import of **LINAGLIPTIN** (0.350 Kg, Invoice # 202110329) and attested copy of form 6 (I&E) DRAP, Islamabad dated 08-03-2021.

10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.2 Metformin HCl**	Justify for performance of assay via potentiometric titration, since the USP recommended HPLC method for assay testing of metformin HCl.	Firm replied that they have now performed the assay of metformin HCl via HPLC method as per USP 43 and accordingly performed the verification studies of assay procedure on HPLC.
2.	**3.2.S.4.2 Linagliptin**	Justify for using different method for performing the enantiomeric purity test from that specified by the drug substance manufacturer. Further, submit the evidence of availability of chiral HPLC (chiral Pak AD column) as you have mentioned in the procedure of enantiomeric purity test.	Firm again submitted the procedure of enantiomeric purity test which is different from the procedure followed by the drug substance manufacturer.
3.	**3.2.S.7**	Please confirm the claimed re-test period of empagliflozin and linagliptin, accordingly provide the stability data of long term till the claimed re-test date.	Firm submitted the stability data of both drug substance.
4.	**3.2.P.1**	Justify the double film coating on the core of metformin comparing the formulation of innovator product in which single film coating has been done on the core of metformin.	Firm replied that " we have performed drug coating of empagliflozin and Lina gliptin in single step as performed by innovator and then finish coat (film coating) is done in order to protect the drug coating and smoothen the final tablets.
5.	**3.2.P.5.1**	Justify for not including the arginine content test and water content in the finished product specification since these test are included in the specification of finished product of innovator product.	Firm replied that they now included the arginine content test and water content in the finished product specification since these tests are included in the specification of finished product of innovator product. Firm submitted the procedure of arginine content and water content test.
6.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submitted the stability data performed at long term stability condition till 12 months.
7.	**3.2.R.1.1**	Scientific justification is required for using 10% excess quantity of linagliptin and empagliflozin in the trail batches as evident from the submitted Batch manufacturing record comparing the review literature of innovator brand in which the composition did not mentioned	Firm replied that to compensate the machine loss in coating they use 10% excess quantity of linagliptin and empagliflozin.

		the excess amount of said active ingredients.	

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.

953.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 796 date of submission: 10-01-2022
	Details of fee submitted	PKR 75,000/-: dated 28/12/2021
	The proposed proprietary name / brand name	Segana XR 12.5mg/2.5mg/1000mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Empagliflozin….12.5mg Linagliptin…….2.5mg Metformin HCL……1000mg (as extended release)
	Pharmaceutical form of applied drug	Tablet, Extended Release
	Pharmacotherapeutic Group of (API)	**Metformin HCL** biguanide class of antidiabetics **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors.
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR Tablet of BOEHRINGER INGELHEIM (FDA approved)
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-01-2024.
	Name and address of API manufacturer.	<u>EMPAGLIFLOZIN:</u> • Fuxin long rui pharmaceutical Co., Ltd. <u>METFORMIN HCL:</u>

		• Aarti drugs limited LINAGLIPTIN: • M/s. Venkata Narayana Active Ingredients
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 66 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **EMPAGLIFLOZIN** Batches: (20160606, 20161017, 20161219) **METFORMIN HCL** Batches: (MEF/1410027 MEF/1410028, MEF/1410029) **LINAGLIPTIN** batches: (LNG20131220 LNG20141220, LNG20151220)
	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	The Firm has performed pharmaceutical equivalence profile of their developed formulation Segana XR 5mg/2.5mg/1000mg tablet (B #ST21H005) with innovator product Trijardy XR Tablets (B # 3187791) of M/s Boehringer Ingelheim Pharma, USA. The results showed that release profile of both test and comparator products were comparable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	EMPAGLIFLOZIN:	

		• Manufacturer: FUXIN LONG RUI PHARMACEUTICAL Co., Ltd. METFORMIN HCL: • Manufacturer: AARTI DRUGS LIMITED LINAGLIPTIN: • Manufacturer: M/s. Venkata Narayana Active Ingredients		
API Lot No.		(Empagliflozin): E-20190920-D02-E06-01 (Metformin HCL): MEF/10030953 (Linagliptin): LG0131220		
Description of Pack (Container closure system)		HDPE bottles (30's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 36 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,18, 24 & 36 (Months)		
Batch No.		ST21H003	ST21H003	ST21H003
Batch Size		3000 tablets	3000 tablets	3000 tablets
Manufacturing Date		08-2021	08-2021	08-2021
Date of Initiation		01-09-2021	01-09-2021	01-09-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**EMPAGLIFLOZIN:** Copy of GMP issued by Food & drug authority china valid till 23/08/2023. **METFORMIN HCL:** Copy of GMP certificate No. 20031933 issued by Food & drug Control Administration valid till 19/03/2023. **LINAGLIPTIN:** Copy of GMP certificate issued by drug Control Administration Andhra Pradesh valid till 07/12/2024.		

3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of **EMPAGLIFLOZIN** (1.5 Kg, Invoice # HN19120501-H) and attested copy of form 6 (I&E) DRAP, Islamabad dated 10-01-2020. The firm has submitted copy of invoice for the import of **METFORMIN HCL** (1000 Kg, Invoice # EXP/302/20-21) and attested copy of form 6 (I&E) DRAP, Islamabad dated 05-08-2020. The firm has submitted copy of invoice for the import of **LINAGLIPTIN** (0.350 Kg, Invoice # 202110329) and attested copy of form 6 (I&E) DRAP, Islamabad dated 08-03-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.2 Metformin HCl**	Justify for performance of assay via potentiometric titration, since the USP recommended HPLC method for assay testing of metformin HCl.	Firm replied that they have now performed the assay of metformin HCl via HPLC method as per USP 43 and accordingly performed the verification studies of assay procedure on HPLC.
2.	**3.2.S.4.2 Linagliptin**	Justify for using different method for performing the enantiomeric purity test from that specified by the drug substance manufacturer. Further, submit the evidence of availability of chiral HPLC (chiral Pak AD column) as you have mentioned in the procedure of enantiomeric purity test.	Firm again submitted the procedure of enantiomeric purity test which is different from the procedure followed by the drug substance manufacturer.
3.	**3.2.S.7**	Please confirm the claimed re-test period of empagliflozin and linagliptin, accordingly provide the stability data of long term till the claimed re-test date.	Firm submitted the stability data of both drug substance.
4.	**3.2.P.1**	Justify the double film coating on the core of metformin comparing the formulation of innovator product in which single film coating has been done on the core of metformin.	Firm replied that " we have performed drug coating of empagliflozin and Lina gliptin in single step as performed by innovator and then finish coat (film coating) is done in order to protect the drug coating and smoothen the final tablets.
5.	**3.2.P.5.1**	Justify for not including the arginine content test and water content in the finished product specification since these test are included in the specification of finished product of innovator product.	Firm replied that they now included the arginine content test and water content in the finished product specification since these tests are included in the specification of finished product of innovator product. Firm submitted the procedure of arginine content and water content test.

6.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submitted the stability data performed at long term stability condition till 12 months.
7.	**3.2.R.1.1**	Scientific justification is required for using 10% excess quantity of linagliptin and empagliflozin in the trail batches as evident from the submitted Batch manufacturing record comparing the review literature of innovator brand in which the composition did not mentioned the excess amount of said active ingredients.	Firm replied that to compensate the machine loss in coating they use 10% excess quantity of linagliptin and empagliflozin.

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.

954.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.797 date of submission: 10-01-2022
	Details of fee submitted	PKR 75,000/-: dated 28/12/2021
	The proposed proprietary name / brand name	Segana XR 25mg/5mg/1000mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Empagliflozin….25mg Linagliptin…….5mg Metformin Hcl……..1000mg (as extended release)
	Pharmaceutical form of applied drug	Tablet, Extended Release
	Pharmacotherapeutic Group of (API)	**Metformin HCL** biguanide class of antidiabetics **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. **Linagliptin:** dipeptidyl peptidase-4 (DPP-4) inhibitors.
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	30’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR Tablet of BOEHRINGER INGELHEIM (FDA approved)
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-01-2024.
	Name and address of API manufacturer.	EMPAGLIFLOZIN: • Fuxin long RUI pharmaceutical Co., Ltd. METFORMIN HCL: • Aarti drugs limited LINAGLIPTIN: • M/s. Venkata Narayana Active Ingredients
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months **EMPAGLIFLOZIN** Batches: (20160606, 20161017, 20161219) (24 months) **METFORMIN HCL** Batches: (MEF/1410027 MEF/1410028, MEF/1410029) (48 months) **LINAGLIPTIN** batches: (LNG20131220 LNG20141220, LNG20151220)(9 months)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence profile of their developed formulation Segana XR 25mg/5mg/1000mg tablet (B #ST21G026) with innovator product

		Trijardy XR Tablets (B # 3185607) of M/s Boehringer Ingelheim Pharma, USA. The results showed that release profile of both test and comparator products were comparable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	EMPAGLIFLOZIN: • Manufacturer: FUXIN LONG RUI PHARMACEUTICAL Co., Ltd. METFORMIN HCL: • Manufacturer: AARTI DRUGS LIMITED LINAGLIPTIN: • Manufacturer: M/s. Venkata Narayana Active Ingredients		
API Lot No.	(Empagliflozin): E-20190920-D02-E06-01 (Metformin HCL): MEF/10030953 (Linagliptin): LG0131220		
Description of Pack (Container closure system)	HDPE bottles (30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 36 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,18, 24 & 36 (Months)		
Batch No.	ST21G026	ST21G026	ST21G026
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	17-08-2021	17-08-2021	17-08-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**EMPAGLIFLOZIN:** Copy of GMP issued by Food & drug authority china valid till 23/08/2023. **METFORMIN HCL:** Copy of GMP certificate No. 20031933 issued by Food & drug Control Administration valid till 19/03/2023. **LINAGLIPTIN:**

		Copy of GMP certificate issued by drug Control Administration Andhra Pradesh valid till 07/12/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of **EMPAGLIFLOZIN** (1.5 Kg, Invoice # HN19120501-H) and attested copy of form 6 (I&E) DRAP, Islamabad dated 10-01-2020. The firm has submitted copy of invoice for the import of **METFORMIN HCL** (1000 Kg, Invoice # EXP/302/20-21) and attested copy of form 6 (I&E) DRAP, Islamabad dated 05-08-2020. The firm has submitted copy of invoice for the import of **LINAGLIPTIN** (0.350 Kg, Invoice # 202110329) and attested copy of form 6 (I&E) DRAP, Islamabad dated 08-03-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.4.2 Metformin HCl**	Justify for performance of assay via potentiometric titration, since the USP recommended HPLC method for assay testing of metformin HCl.	Firm replied that they have now performed the assay of metformin HCl via HPLC method as per USP 43 and accordingly performed the verification studies of assay procedure on HPLC.
2.	**3.2.S.4.2 Linagliptin**	Justify for using different method for performing the enantiomeric purity test from that specified by the drug substance manufacturer. Further, submit the evidence of availability of chiral HPLC (chiral Pak AD column) as you have mentioned in the procedure of enantiomeric purity test.	Firm again submitted the procedure of enantiomeric purity test which is different from the procedure followed by the drug substance manufacturer.
3.	**3.2.S.7**	Please confirm the claimed re-test period of empagliflozin and linagliptin,accordingly provide the stability data of long term till the claimed re-test date.	Firm submitted the stability data of both drug substance.
4.	**3.2.P.1**	Justify the double film coating on the core of metformin comparing the formulation of innovator product in which single film coating has been done on the core of metformin.	Firm replied that " we have performed drug coating of empagliflozin and Lina gliptin in single step as performed by innovator and then finish coat (film coating) is done in order to protect the drug coating and smoothen the final tablets.

5.	**3.2.P.5.1**	Justify for not including the arginine content test and water content in the finished product specification since these test are included in the specification of finished product of innovator product.	Firm replied that they now included the arginine content test and water content in the finished product specification since these tests are included in the specification of finished product of innovator product. Firm submitted the procedure of arginine content and water content test.
6.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submitted the stability data performed at long term stability condition till 12 months.
7.	**3.2.R.1.1**	Scientific justification is required for using 10% excess quantity of Linagliptin and Empagliflozin in the trail batches as evident from the submitted Batch manufacturing record comparing the review literature of innovator brand in which the composition did not mentioned the excess amount of said active ingredients.	Firm replied that to compensate the machine loss in coating they use 10% excess quantity of Linagliptin and Empagliflozin.

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.

955.	Name, address of Applicant / Marketing Authorization Holder	M/s. W. Woodward Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi
	Name, address of Manufacturing site.	M/s. W. Woodward Pakistan (Pvt.) Ltd. F-275, S.I.T.E. Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1453 date of submission: 29-11-2021
	Details of fee submitted	PKR 30,000/-: dated 17/01/2022
	The proposed proprietary name / brand name	**Tilva tablet 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Levosulpiride….50mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	**Selective antagonist of Dopamine D2 receptor**
	Reference to Finished product specifications	Manufacturer's specs
	Proposed Pack size	20 tablets in alu-alu blister (10x2)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levopraid Tablet (Italy agency approved) But the record has not found)
	For generic drugs (me-too status)	N/A

	GMP status of the Finished product manufacturer	Firm submitted the copy of routine inspection report conducted on 02-07-2020 concluded with the remarks that firm is found maintaining good level of GMP.
	Name and address of API manufacturer.	M/s. Atlas Life Sciences Pvt. Ltd. C-1/360-361, G.I.D.C Estate, Odhav, Ahmedabad Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & 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 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 12 months Batches: LPS-0010415, LPS-0020515, LPS-0030515
	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	The Firm has performed pharmaceutical equivalence profile of their developed formulation with REFERENCE product Sulvorid tablet 50mg and performed comparative dissolution profile against the same reference product an three recommended dissolution medium.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s. Atlas Life Sciences Pvt. Ltd. C-1/360-361, G.I.D.C Estate, Odhav, Ahmedabad Gujrat India
API Lot No.	LSP-1910020
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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PD-186	PD-187	PD-188
Batch Size	400 tablets	400 tablets	400 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	12-09-2020	12-09-2020	12-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate of API manufacturer M/s. Atlas Life Sciences Pvt. Ltd. C-1/360-361, G.I.D.C Estate, Odhav, Ahmedabad Gujrat India is submitted which was valid till 10/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the copy of letter of Mansoor chemicals as an evidence of procurement of API which was without DRAP attestation /approval.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of your application.	

Decision: Deferred for evaluation of submitted data as per the CTD guidance document approved by Registration Board.

956.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3113 dated 31-01-2022
	Details of fee submitted	Rs.75,000/- dated 25-01-2022
	The proposed proprietary name / brand name	**Azila-C Tablet 40mg/12.5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Azilsartan Medoxomil as Potassium.....40mg Chlorthalidone……..12.5mg
	Pharmaceutical form of applied drug	Oral solid dosage form
	Pharmacotherapeutic Group of (API)	**Azilsartan Medoxomil Potassium** Angiotensin II antagonist
		Chlorthalidone Benzothiadiazine Diuretic
	Reference to Finished product specifications	As Per Innovator Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**EDARBYCLOR Tablet 40mg/12.5mg** approved by **US-FDA**
	For generic drugs (me-too status)	N/A (as it is New Drug Product)
	GMP status of the Finished product manufacturer	Last inspection report dated 14.10.2021 concluded good level of cGMP compliance.
	Name and address of API manufacturer.	**Azilsartan Medoxomil Potassium** **CTX Life Sciences Pvt Ltd** Block no: 251-252-Sachin-Magdalla Road GIDC Sachin, Surat-394 230 Gujrat India **Chlorthalidone** **Menadiaona S.L** Poligon Industrial Mas Puigvert s/n,08389 Palafolls, Barcelona, Spain
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, 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 General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.
	Stability studies	***Azilsartan Medoxomil Potassium*** Stability study conditions: Real time: 5˚C ± 3˚C Accelerated: 25˚C ± 2˚C / 60% ± 5%RH

Batch No	Accelerated	Long Term
AK180002	6 Months	72 Months

		AK180003 | 6 Months | 72 Months AK180004 | 6 Months | 72 Months ***Chlorthalidone*** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH **Batch No** | **Accelerated** | **Long Term** CLT/20100201 | 6 Months | 24 Months CLT/20100301 | 6 Months | 24 Months CLT/20100302 | 6 Months | 24 Months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **EDARBYCLOR Tablets 40mg/12.5mg (Batch No: 482312) by Takeda Pharmaceuticals** by performing quality tests (Identification, Assay, and Dissolution. CDP has been performed against the same brand that is in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA

Manufacturer of API	Azilsartan Medoxomil Potassium	Chlorthalidone	
	CTX Life Sciences Pvt Ltd	Menadiaona S. L	
API Lot No.	19AK00013	4180/91405	
Description of Pack (Container closure system)	Alu-Alu Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24(Months)		
Batch No.	**ACL-001**	**ACL-002**	**ACL-003**
Batch Size	1500 Tab	1500 Tab	1500 Tab
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	27-08-2020	30-08-2020	02-09-2020
No. of Batches	03		

Administrative Portion

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td>Firm has referred to onsite inspection report of their product:

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules
(Dexlansoprazole)

which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021.
Registration Board decided to approve registration of

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules
(Dexlansoprazole)

by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following two observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
iv. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg.
Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Azilsartan Medoxomil Potassium: Firm had provided valid GMP & DML Certificate of CTX Life Sciences Pvt Ltd.DML Valid Up-To: 23- 01- 2026
GMP Valid Up-To: 01- 07- 2022
Chlorthalidone: Firm had provided valid GMP & DML Certificate of Menadiona S.L DML Valid Up-To: 31-01- 2022
GMP Valid Up-To: 31-03- 2022</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted
<table>
<tr><th>Name of API</th><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>Azilsartan Medoxomil Potassium</td><td>19AK00013</td><td>E1/3092100609</td><td>1.5kg</td><td>24-01-2020</td></tr>
<tr><td>Chlorthalidone</td><td>4180/91405</td><td>201138</td><td>540g</td><td>19-05-2020</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like</td><td>Submitted</td></tr>
</table>

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

Remarks of Evaluator:

INDICATIONS AND USAGE:

Edarbyclor is an angiotensin II receptor blocker (ARB) and a thiazide like diuretic combination product indicated for the treatment of hypertension, to lower blood pressure:

• In patients not adequately controlled with monotherapy

• As initial therapy in patients likely to need multiple drugs to help achieve blood pressure goals

Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

DOSAGE AND ADMINISTRATION:

• Starting dose is 40/12.5 mg once daily

• Edarbyclor may be used to provide additional blood pressure lowering for patients not adequately controlled on azilsartan medoxomil 80 mg or chlorthalidone 25 mg

• Dose may be increased to 40/25 mg after 2 to 4 weeks as needed to achieve blood pressure goals

• Maximal dose is 40/25 mg

• May be administered with other antihypertensive agents

• Edarbyclor may be administered with or without food

• Replace volume in volume-depleted patients prior to use

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.

957.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3114 dated 31-01-2022

	Details of fee submitted	Rs.75,000/- dated 25-01-2022	
	The proposed proprietary name / brand name	**Azila-C Tablet 40mg/25mg**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Azilsartan Medoxomil as Potassium.....40mg Chlorthalidone…….25mg	
	Pharmaceutical form of applied drug	Oral solid dosage form	
	Pharmacotherapeutic Group of (API)	Azilsartan Medoxomil Potassium Angiotensin II antagonist	
		Chlorthalidone Benzothiadiazine Diuretic	
	Reference to Finished product specifications	As Per Innovator Specs	
	Proposed Pack size	As per SRO	
	Proposed unit price	As per SRO	
	The status in reference regulatory authorities	EDARBYCLOR Tablet 40mg/25mg approved by US-FDA	
	For generic drugs (me-too status)	N/A (as it is New Drug Product)	
	GMP status of the Finished product manufacturer	Last inspection report dated 14.10.2021 concluded good level of cGMP compliance.	
	Name and address of API manufacturer.	Azilsartan Medoxomil Potassium CTX Life Sciences Pvt Ltd Block no: 251-252-Sachin-Magdalla Road GIDC Sachin, Surat-394 230 Gujrat India	Chlorthalidone Menadiaona S.L Poligon Industrial Mas Puigvert s/n,08389 Palafolls, Barcelona, Spain
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, 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 General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.	
	Stability studies	Azilsartan Medoxomil Potassium Stability study conditions: Real time: 5˚C ± 3˚C Accelerated: 25˚C ± 2˚C / 60% ± 5%RH Azilsartan Medoxomil Potassium	

Batch No	Accelerated	Long Term
AK180002	6 Months	72 Months
AK180003	6 Months	72 Months
AK180004	6 Months	72 Months

		Chlorthalidone Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Batch No	Accelerated	Long Term
CLT/20100201	6 Months	24 Months
CLT/20100301	6 Months	24 Months
CLT/20100302	6 Months	24 Months

	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is EDARBYCLOR Tablets 40mg/25mg (Batch No: 483795) by Takeda Pharmaceuticals by performing quality tests (Identification, Assay, and Dissolution. CDP has been performed against the same brand that is in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA

Manufacturer of API	Azilsartan Medoxomil Potassium		Chlorthalidone
	CTX Life Sciences Pvt Ltd		Menadiaona S. L
API Lot No.	19AK00013		4180/91405
Description of Pack (Container closure system)	Alu-Alu Blisters with aluminium foil having leaflet and packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24(Months)		
Batch No.	ACH-001	ACH-002	ACH-003
Batch Size	1500 Tab	1500 Tab	1500 Tab
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	03-09-2020	07-09-2020	09-09-2020
No. of Batches	03		

<table>
<tr><td colspan="4">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="2">Firm has referred to onsite inspection report of their product:

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole)

which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021.
Registration Board decided to approve registration of

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole)

by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following two observations were reported in the report:
v. The HPLC software is 21 CFR compliant.
vi. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available.
vii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
viii. Verification of performance of dissolution test at buffer stage
pH 5.5 for Dayzol Capsules 30mg and 60mg.
Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.</td></tr>
<tr><td rowspan="2">2.</td><td rowspan="2">Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Azilsartan Medoxomil Potassium</td><td>Chlorthalidone</td></tr>
<tr><td>Firm had provided valid GMP & DML Certificate of CTX Life Sciences Pvt Ltd

DML Valid upto: 23- 01- 2026
GMP Valid upto: 01- 07- 2022</td><td>Firm had provided valid GMP & DML Certificate of Menadiona S.L

DML Valid upto: 31-01- 2022
GMP Valid upto: 31-03- 2022</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted
<table>
<tr><th>Name of API</th><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>Azilsartan Medoxomil Potassium</td><td>19AK00013</td><td>E1/3092100609</td><td>1.5kg</td><td>24-01-2020</td></tr>
</table></td></tr>
</table>

		<table><tr><td>Chlorthalidone</td><td>4180/91405</td><td>201138</td><td>540g</td><td>19-05-2020</td></tr></table>
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports have been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Sr.no.	Section	Observation	Firm's response
1.	**1.6.5**	Valid GMP certificate for the drug substance manufacturer of Chlorthalidone, issued by the relevant regulatory authority shall be submitted.	Firm submitted the updated GMP certificate of drug substance manufacturer of chlorthalidone.
2.	**3.2.S.4.3**	Clarification shall be submitted for the composition of placebo solution used for the performance of specificity parameter in the analytical method verification studies of drug substance.	Firm submitted the composition of placebo solution used for the performance of specificity parameter in the analytical method verification studies of drug substance.
3.	**3.2.P.2.2.1**	• Details shall be submitted for the dissolution parameters applied for the performance of CDP studies. • Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution medium while referring to the innovator drug product literature wherein both the drug substances have been reported as BCS Class IV drug substances and Azilsartan has been declared as practically insoluble in acidic aqueous solutions.	Firm submitted the details of dissolution parameters applied for the performance of CDP studies. Firm submitted the reply that "for the performance of CDP Studies the standard solution was prepared in the same medium i.e., 0.1N HCL, hence the results are relative to the absorbance of standard solution. We are hereby submitting the CDP studies with standard solution prepared with diluents other than dissolution medium". Further, firm submitted report of CDP studies which has been performed with aid of surfactant.
4.	**3.2.P.5.3**	• Justification shall be submitted for the limits of peak purity test applied in the performance of specificity parameter in the analytical method validation studies. • Evidence of availability of HPLC equipped with PDA/ DAD detector applied for the performance of specificity parameter in the analytical method validation studies shall be submitted.	• Firm replied that Peak purity is calculated through software 98-100% is acceptable limit for peak purity • Further firm submitted the Spectrum which prove system equipped with PDA detector.
5.	**3.2.P.6**	COA of primary / secondary reference standard including source and lot number shall be provided.	Firm submitted the COA of primary / secondary reference standard.

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.

Cases of export facilitation:

958.	**Export Facilitation:** Applications was received through letter No.F.1-76/2019-PR-I (EFD) "M/s Pharmedic Laboratories (Pvt.) Ltd. have achieved benchmark OF USD 1576776.335 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 02 products applications submitted by the firm."	
	Name, address of Applicant / Marketing Authorization Holder	**Name:** Pharmedic Laboratories (Pvt.) Ltd. **Address:** 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	**Name:** Pharmedic Laboratories (Pvt.) Ltd. **Address:** 16km Multan Road, Lahore-Pakistan **Contact details: Tel: +92** 42 37511861-65
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.11999 dated 17/05/2022
	Details of fee submitted	PKR 30,000/-: dated 07/04/2022
	The proposed proprietary name / brand name	Axaban 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban……2.5mg
	Pharmaceutical form of applied drug	Pink colored, round shaped, biconvex film coated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's , 14's and 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bristol-Myers Squibb Company, USA (USFDA Approved) Bristol-Myers Squibb/Pfizer EEIG, Ireland
	For generic drugs (me-too status)	Elixaban Tablet 2.5mg (Reg.no. 105238) of M/s. Martin Dow Limited Karachi
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	**Name:** Jiangsu Yongan Pharmaceuticals Co., Ltd **Address:** No. 18, 237 Provincial Road, Economic Development zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (23111001,2311102,23111101)
	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 Eliquis 2.5mg Tablet by Pfizer Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Eliquis 2.5mg Tablet by Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland……. 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 Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu Yongan Pharmaceuticals Co., Ltd		
API Lot No.	APB-202004002		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (10's , 14's and 20's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6(Months)		
Batch No.	Apx2.5-TR004	Apx2.5-TR005	Apx2.5-TR006
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-2021	10-2021	10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NIL issued by Huai'an Pharmaceutical Industry Association valid till 14/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.10927/2020DRAP-AD (I&E) dated 07/08/2020 is submitted wherein the permission to import Apixaban for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2. S.4.3**	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.
2.	**3.2.P.2.2.1**	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.
3.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

959.	Name, address of Applicant / Marketing Authorization Holder	**Name:** Pharmedic Laboratories (Pvt.) Ltd. **Address:** 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	**Name:** Pharmedic Laboratories (Pvt.) Ltd. **Address:** 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no. 12000 dated 17/05/2022
	Details of fee submitted	PKR 30,000/-: dated 17/05/2022
	The proposed proprietary name / brand name	**Axaban 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban……5mg
	Pharmaceutical form of applied drug	Orange red colored, round shaped, biconvex film coated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's , 14's and 20's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bristol-Myers Squibb Company, USFDA Approved Bristol-Myers Squibb/Pfizer EEIG, Ireland
	For generic drugs (me-too status)	Elixaban Tablet 5mg (Reg.no. 105237) of M/s. Martin Dow Limited Karachi
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	**Name:** Jiangsu Yongan Pharmaceuticals Co., Ltd **Address:** No. 18, 237 Provincial Road, Economic Development zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (23111001,2311102,23111101)
	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 Eliquis 5mg Tablet by Pfizer Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Eliquis 5mg Tablet by Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland……. 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 Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	Jiangsu Yongan Pharmaceuticals Co., Ltd

API Lot No.	APB-202004002		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (10's , 14's and 20's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	Apx5-TR001	Apx5-TR002	Apx5-TR003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-2021	10-2021	10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NIL issued by Huai'an Pharmaceutical Industry Association valid till 14/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.10927/2020DRAP-AD (I&E) dated 07/08/2020 is submitted wherein the permission to import Apixaban for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2. S.4.3**	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.
2.	**3.2.P.2.2.1**	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.
3.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

960.	**Export Facilitation:** Applications was received through letter No.F.1-6/2019-PR-I (EFD) dated 28th Feb,2023 "M/s Ferozsons Laboratories Limited, have achieved benchmark OF USD 2108059.57 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 1 products applications submitted by the firm."	
	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30785 dated 31-10-2022
	Details of fee submitted	PKR 75,000/-: dated 27/09/2022
	The proposed proprietary name / brand name	APRIVA TABLETS COMBO PACK
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Combo pack contains: **04 Tablets of Apremilast 10** **Each film coated tablets contains:** Apremilast …..10mg **04 Tablets of Apremilast 20** **Each film coated tablets contains:** Apremilast ….20mg **47 Tablets of Apremilast 30** **Each film coated tablets contains:** Apremilast ….30mg Combo pack contains: **04 Tablets of Apremilast 10** **Each film coated tablets contains:** Apremilast ….10mg **04 Tablets of Apremilast 20** **Each film coated tablets contains:** Apremilast ….20mg **19 Tablets of Apremilast 30** **Each film coated tablets contains:** Apremilast …..30mg
	Pharmaceutical form of applied drug	Apriva Tablets 10mg: Brown Round, 5.5.mm biconvex film coated tablet with "*f*" on one side and plain on other side Apriva Tablets 20mg: Brown, Round, 8mm biconvex film coated tablet with "*f*" on one side and plain on other side Apriva Tablets 30mg: Brown Round, 9.5mm biconvex film coated tablet with "*f*" on one side and plain on other side
	Pharmacotherapeutic Group of (API)	Antineoplastic and Immunomodulating Agents
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	**Combo pack** 04 tablets of 10mg 04 tablets of 20mg 47 tablets of 30mg **Combo pack** 04 tablets of 10mg 04 tablets of 20mg 19 tablets of 30mg Total 27 Tablets
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	OTEZLA TABLETS BY Amgen Inc. (USFDA Approved)
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP certificate No. F. 11-6/2021-DRAP-65 granted on 25/08/2021 Valid up to 10-08-2023. Tablet (General) section approved vide letter No. F.3-14/2004-Lic, dated: 08-04-2015 is submitted.
	Name and address of API manufacturer.	Glenmark Life Sciences Limited Address: Plot No. Z-103-I, SEZ Phase II, Dahej, Taluka Vagra, District Bharuch, Gujarat – 392 130, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/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 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(AMTab-001, AMTab-002, AMTab-003) (AMTab-004, AMTab-005, AMTab-006) (AMTab-007, AMTab-008, AMTab-009)
	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 Otezla Tablets by Amgen Inc. (USA), by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Otezla Tablets by Amgen Inc. (USA). The dissolution profile has shown release less than 85 % in all three Buffer pH 1.2, Phosphate Buffer pH 6.8 and Acetate Buffer pH 4.5 in 15 minutes and similarity factor f2 calculated which complies acceptance criteria. Hence dissolution profile of both Apriva tablets and Otezla Tablet found similar.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Glenmark Life Sciences Limited Address: Plot No. Z-103-I, SEZ Phase II, Dahej, Taluka Vagra, District Bharuch, Gujarat – 392 130, India.		
API Lot No.	82190049		
Description of Pack (Container closure system)	Apremilast Tablets 10mg: Alu-PVDC blister of 10 Tablets Apremilast Tablets 20mg: Alu-PVDC blister of 10 Tablets Apremilast Tablets 30mg: Alu-PVDC blister of 10 Tablets		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Apremilast Tablets 10mg AMTab-001, AMTab-002, AMTab-003.	Apremilast Tablets 20mg AMTab-004, AMTab-005, AMTab-006.	Apremilast Tablets 30mg AMTab-007, AMTab-008, AMTab-009.
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	19-09-2020	19-09-2020	19-09-2020
No. of Batches	09		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21082834 issued by Food and Drug Controls Administration, Block No.8, 1st floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujrat State, India valid till 06/08/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form-6, No.00198/2019-DRAP (Ps)/817 dated 26/02/2019, DRAP acknowledgment for receiving of Apremilast, Commercial invoice, packing list, Form-3 & Form-7 and Goods declarations is submitted wherein the permission to import Apremilast for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.P.5.2**	Justify for not adopting the updated dissolution condition of Apremilast tablet as specified in the dissolution database of USFDA.	Firm replied that the product is also tested by adopting updated dissolution conditions of Apremilast tablet as specified in the dissolution database of USFDA and found complies, result for the same along with chromatogram is attached.
2.	**3.2.P.7**	Please submit the revised packaging presentation of combo pack in compliance of decision of 321st meeting of Registration Board related	Firm submit the **primary packaging presentation for 14 days starter pack** i.e. 01 alu-PVDC blister 13 tablets (04 tablets of Apremilast 10mg, 04 tablets of Apremilast 20mg

		to presentation/pack size of Apremilast tablet.	and 05 tablets of Apremilast 30mg) and 01 Alu-pvdc blister of 14 tablets of Apremilast 30mg, both the blisters placed in their respective pouch (secondary packaging). **Primary Packaging presentation of 28 days starter pack:** Primary packaging presentation for 14 days starter pack i.e. 01 alu-PVDC blister 13 tablets (04 tablets of Apremilast 10mg, 04 tablets of Apremilast 20mg and 05 tablets of Apremilast 30mg) and 03 Alu-pvdc blister of 14 tablets of Apremilast 30mg both the blisters placed in their respective pouch (secondary packaging).

Decision: Approved.

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

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

Registration letter will be issued upon confirmation of availability of "Co-blistering" facility.

961. **Export Facilitation:** Applications was received through letter No.F.1-6/2019-PR-I (EFD) "M/s. SAMI Pharmaceuticals (Pvt.) Ltd. have achieved benchmark OF USD 1596135.35 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 02 products applications submitted by the firm."

Name, address of Applicant / Marketing Authorization Holder	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi.**
Name, address of Manufacturing site.	M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi – 75730, 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. 31975 dated 04/11/2022
Details of fee submitted	PKR 30,000/-: dated 29/08/2022
The proposed proprietary name / brand name	**ONDIS 4mg/2ml Injection**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Ondansetron Hydrochloride USP equivalent to Ondansetron…… 4mg USP specs
Pharmaceutical form of applied drug	Clear, colorless solution for injection
Pharmacotherapeutic Group of (API)	Antiemetic and Serotonin (5HT3) antagonists
Reference to Finished product specifications	USP
Proposed Pack size	1's & 5's
Proposed unit price	As per SRO
The status in reference regulatory authorities	Zofran Injection 4mg/2ml by Novartis Pharma UK Ltd
For generic drugs (me-too status)	Zofran Injection 4mg/2ml by Novartis Pharma (Pakistan) Ltd, Regn. no. 052259
GMP status of the Finished product manufacturer	GMP certificate issue date 03-08-2022
Name and address of API manufacturer.	**Cadila Pharmaceuticals Limited.** 294, G.I.D.C. Estate Ankleshwar - 393 002 .Gujarat, INDIA

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurity and related substances, specifications, analytical procedures and its Verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 Months Batches: (17OS001, 17OS002) Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (15OS003, 15OS004, 15OS005) Declaration regarding stability study data is provided in dossier
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product i.e. **ZOFRAN Injection 4mg/2ml** by **M/s. Novartis Pharma (Pak) Ltd** by performing quality tests (Appearance, Clarity, Identification, Assay, pH, Osmolarity, Wt/ml, Extractible volume, Chromatographic impurities, Sterility, Particulate Matter and Bacterial Endotoxin Test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision including repeatability & specificity.

STABILITY STUDY DATA

Manufacturer of API	**Cadila Pharmaceuticals Limited.** 294, G.I.D.C. Estate Ankleshwar - 393 002 .Gujarat, INDIA		
API Lot No.	20OS001		
Description of Pack (Container closure system)	Unprinted clear Ampoules 3ml USP Type-I		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-16	Lab-17	Lab-18

Batch Size	1.700 L	1.700 L	1.700 L
Manufacturing Date	Nov 2021	Nov 2021	Nov 2021
Date of Initiation	Dec 2021	Dec 2021	Dec 2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Reference of our last onsite panel inspection for instant dosage form conducted during last two years i.e. IBRUO (Ibuprofen) 800mg/100 ml injection which was presented in 289th meeting of the registration board & hence approved & registered by registration board Date of inspection: 28th January 2019. The inspection report confirms following points • The HPLC software is 21CFR Compliant. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21102987 issued by FOOD AND DRUGS CONTROL ADMINISTRATION Gujarat State valid till 20/10/2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Detail of loan material (200gm of Ondansetron HCl) from M/s Indus Pharma (Pvt.) Ltd. of the lot supplied by M/s. Cadila Pharmaceuticals Pvt Limited under their invoice no. 3202040403 dated 10-07-2020 attested by AD (I&E), Karachi dated 19-08-2020. (MOU regarding procuring material on loan provided in dossier)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2. S.4.2**	According to the USP monograph of ondansetron water content limit is NMT 3.0%, justify for keeping the acceptance limit of water content between 9.0 to 10.5% for drug substance complying USP specification.	Firm reply that "In the USP, there are two separate monographs for ondansetron i.e., Ondansetron and Ondansetron HCl. According to the USP monograph of ondansetron water content limit is **NMT 3.0%** Whereas for Ondansetron HCl water content between **9.0% to 10.5%** We have used Ondansetron HCl in our formulation same as of Innovator products i.e. ZOFRAN, approved by USFDA. We have claimed the same API in our Invoice, label claim, BPIs, SPTM & Stability Sheets as well. Hence we comply with USP monograph.

2.	**3.2.S.7**	Submit stability data of three batches of drug substance performed at long term stability conditions.	Firm submit stability data with the statement that "We have submitted Long Term stability data of 36 month on zone IV-B 30 ±2ºC, 75 ±5% RH for batches 17OS001 and 17OS002 in dossier along with a declaration by M/s. Cadila Pharmaceutical that they will charge third batch on stability: • As per their Stability intimation sheet third batch was charged on stability on August 2022, • 3rd month stability result of third batch was found satisfactory is now attached. • 6th month stability data due on 3 March 2023 which is under analysis and will be shared by supplier after necessary testing."

Decision: Approved.

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

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

962.	Name, address of Applicant / Marketing Authorization Holder	**M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s. SAMI Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E., Karachi – 75730, 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. 31973 dated 04/11/2022
	Details of fee submitted	PKR 30,000/-: dated 29/08/2022
	The proposed proprietary name / brand name	**ONDIS 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml contains: Ondansetron Hydrochloride USP equivalent to Ondansetron…… 8mg USP specs
	Pharmaceutical form of applied drug	Clear, colorless solution for injection
	Pharmacotherapeutic Group of (API)	Antiemetic and Serotonin (5HT3) antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	1's & 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Injection 8mg/4ml by Novartis Pharma UK Ltd
	For generic drugs (me-too status)	Zofran Injection 8mg/4ml by Novartis Pharma (Pakistan) Ltd, Regn. no. 020669
	GMP status of the Finished product manufacturer	GMP certificate issue date 03-08-2022
	Name and address of API manufacturer.	**Cadila Pharmaceuticals Limited.** 294, G.I.D.C. Estate Ankleshwar - 393 002 .Gujarat, INDIA

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurity and related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 36 Months Batches: (17OS001, 17OS002) Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (15OS003, 15OS004, 15OS005) Declaration regarding stability study data is provided in dossier
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product i.e. **ZOFRAN Injection 8mg/4ml** by **M/s. Novartis Pharma (Pak) Ltd** by performing quality tests (Appearance, Clarity, Identification, Assay, pH, Osmolarity, Wt/ml, Extractible volume, Chromatographic impurities, Sterility, Particulate Matter and Bacterial Endotoxin Test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision including repeatability & specificity.

STABILITY STUDY DATA

Manufacturer of API	**Cadila Pharmaceuticals Limited.** 294, G.I.D.C. Estate Ankleshwar - 393 002 .Gujarat, INDIA		
API Lot No.	20OS001		
Description of Pack (Container closure system)	Unprinted clear Ampoules 5ml USP Type-I		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	3.400 L	3.400 L	3.400 L

Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	May 2021	May 2021	May 2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Reference of our last onsite panel inspection for instant dosage form conducted during last two years i.e. IBRUO (Ibuprofen) 800mg/100 ml injection which was presented in 289th meeting of the registration board & hence approved & registered by registration board Date of inspection: 28th January 2019. The inspection report confirms following points • The HPLC software is 21CFR Compliant. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21102987 issued by FOOD AND DRUGS CONTROL ADMINISTRATION Gujarat State valid till 20/10/2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Detail of loan material (200gm of Ondansetron HCl) from M/s Indus Pharma (Pvt.) Ltd. of the lot supplied by M/s. Cadila Pharmaceuticals Pvt Limited under their invoice no. 3202040403 dated 10-07-2020 attested by AD (I&E), Karachi dated 19-08-2020. (MOU regarding procuring material on loan provided in dossier)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
3.	**3.2. S.4.2**	According to the USP monograph of ondansetron water content limit is NMT 3.0%, justify for keeping the acceptance limit of water content between 9.0 to 10.5% for drug substance complying USP specification.	Firm reply that "In the USP, there are two separate monographs for ondansetron i.e., Ondansetron and Ondansetron HCl. According to the USP monograph of ondansetron water content limit is **NMT 3.0%** Whereas for Ondansetron HCl water content between **9.0% to 10.5%** We have used Ondansetron HCl in our formulation same as of Innovator products i.e. ZOFRAN, approved by USFDA. We have claimed the same API in our Invoice, label claim, BPIs, SPTM & Stability Sheets as well. Hence we comply with USP monograph.
4.	**3.2.S.7**	Submit stability data of three batches of drug substance performed at long term stability conditions.	Firm submit stability data We have submitted Long Term stability data of 36 month on zone IV-B 30 ±2ºC, 75 ±5% RH

			for batches 17OS001 and 17OS002 in dossier along with a declaration by M/s. Cadila Pharmaceutical that they will charge third batch on stability: • As per their Stability intimation sheet third batch was charged on stability on August 2022, • 3rd month stability result of third batch was found satisfactory is now attached. • 6th month stability data due on 3 March 2023 which is under analysis and will be shared by supplier after necessary testing.

Decision: Approved.

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

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

963. **Export Facilitation:** Applications was received through letter No.F.1-6/2019-PR-I (EFD) "M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. have achieved benchmark OF USD 533,670.5 as defined in the Board's decision during fiscal year 2019-2020. In this regard, please find the (1 molecule) 01 products applications submitted by the firm."

Name, address of Applicant / Marketing Authorization Holder	M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. 44-Indutrial Triangle Kahuta Road Islamabad Pakistan
Name, address of Manufacturing site.	M/s M/s Focus & Rulz Pharmaceuticals Pvt., Ltd. 44-Indutrial Triangle Kahuta Road Islamabad Pakistan
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
Dy. No. and date of submission	Dy. No.5220 dated 24-02-2022
Details of fee submitted	PKR 30,000/-: dated 20-05-2022
The proposed proprietary name / brand name	**Delergic Syrup**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Desloratadine USP…… 0.5mg (Innovator Specifications)
Pharmaceutical form of applied drug	Colorless, clear solution, without agglomerate, foreign particles.
Pharmacotherapeutic Group of (API)	Anti-histamine, Anti-allergic
Reference to Finished product specifications	Innovator Specifications
Proposed Pack size	120ml
Proposed unit price	As per SRO
The status in reference regulatory authorities	Clarinex (Desloratadine) Syrup Company: Schering Corporation USFDA Approved
For generic drugs (me-too status)	Jardin-D Syrup 0.5mg/ml by M/s High-Q Pharmaceuticals (Reg.no. 073610).
GMP status of the Finished product manufacturer	DML No 00628 granted on 19/06/2018 (Syrup section is approved).

	Name and address of API manufacturer.	M/s Glenmark Life Sciences Limited, Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakari Audyogik Vasahat, Maryadit, Pune-Hyderabad Highway Mohol – 413213, Dist. Solapur, Maharashtra State, India..
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, 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 as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for Desloratadine,(fluoro Desloratadine, Desloratadine related compound B, & unspecified impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (84160288, 84160291, 84160300)
	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	Not submitted
	Analytical method validation of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Glenmark Life Sciences Limited, Plot no. 141-143, 160-165, 170-172, Chandramouli Sahakari Audyogik Vasahat, Maryadit, Pune-Hyderabad Highway Mohol – 413213, Dist. Solapur, Maharashtra State, India		
API Lot No.	84200308		
Description of Pack (Container closure system)	120ml Amber colored 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.	21CT04	21CT05	21CT06

Batch Size	200 Bottles	200 Bottles	200 Bottles
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	09-04-2021	09-04-2021	09-04-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. MH/102854 issued by CFDA valid till 31/12/2023 submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of ADC approved invoice No.F30000001207, dated 03-12-2020 for 2.0 Kg Desloratadine imported from Glenmark Life Sciences Limited, cleared from DRAP office dated 18-12-2020 submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Stability studies data, supported with Chromatograms and raw data sheets for three batches i.e. 21CT04, 21CT05 and 21CT06 is submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software is 21CFR complaint & complete 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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers is submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**3.2. S.4.3**	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.
2.	**3.2.S.4.4**	Provide COA of drug substance by drug substance manufacturer.
3.	**3.2.S.5**	Submit COA of reference/working standard which was used by drug product manufacturer for analysis of API.
4.	**3.2.P.1**	• Provide compatibility studies of the Drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product. • Formulation contain preservative **sodium benzoate**, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit. • Justify the use of saccharin in the syrup formulation, since the review document of reference product approve in EMA clearly mentioned that *saccharin was not found acceptable from peadriatic point of view*.
5.	**3.2.P.2**	Submit data of Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference/ comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed
6.	**3.2. P.4**	Submit the analysis report/COA of excipients propylene glycol, sorbitol and glycerine, 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.
7.	**3.2.P.5.1**	• According to the review literature of reference product approved in ema stability of active substance is demonstrated to be optimal in a solution with a pH between 5 and 6, Justify for keeping the pH acceptance limit between 4-5.5 when the stability of drug substance is optimized in the solution with a pH between 5 and 6.

		• Justify for not including the test of extractable volume and microbial content test in the finished product specification , since these tests are recommended by the pharmacopeias in their general chapter for oral solution preparation.
8.	**2.3. R.1.1**	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Previously deferred cases of form 5-F:

964.	Name, address of Applicant / Marketing Authorization Holder	M/s. CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Name, address of Manufacturing site.	M/s. CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Status of the applicant	☒ **Manufacture**r ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ **New Drug Product (NDP)** ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No.18317 dated 23/06/2022
	Details of fee submitted	PKR 75,000/-: dated 16/06/2022
	The proposed proprietary name / brand name	**Molvir Capsule 200mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Molnupiravir……200mg (As per innovator Specification)
	Pharmaceutical form of applied drug	White color cap and blue color body, size # 0 having white color powder
	Pharmacotherapeutic Group of (API)	Antiviral
	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	Lagevrio Capsule by Merck sharp & Dohme, UK.
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	GMP certificate granted on 13-05-2019 and valid for three years. Capsule (non-antibiotic) section is included in the GMP certificate.
	Name and address of API manufacturer.	**OPTIMUS DRUGS PRIVATE LIMITED** Survey No. 239 & 240 Dothigudem (V), Pochampally (M),Yadadri-Bhuvanagiri (Dist)-508 284.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)	Molnupiravir is non-pharmacopeial, so firm has to developed manufacturer's specification. 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 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (OP-VICTR-A1-001/21, OP-VICTR-A1-002/21 & OP-VICTR-A1-003/21)
	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 reference product that is Molcovir 200mg Capsule of M/s. Optimus Pharma Pvt. Ltd., India (Batch no. MOLCD1005A) by performing quality tests (Appearance, Identification, weight, disintegration, assay & dissolution test). CDP has been performed against the same reference product 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	**OPTIMUS DRUGS PRIVATE LIMITED** Dothigudem (V), Pochampally (M),Yadadri-Bhuvanagiri (Dist)-508 284.Telangana, INDIA		
API Lot No.	OP-VICTR-A1-040/21		
Description of Pack (Container closure system)	Alu/alu blister in bleach board with 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: 3 months Accelerated: 3 months		
Frequency	Accelerated: 3 & 6(Months) Real Time: 3, 6, 9, 12,18 & 24 (Months)		
Batch No.	T2-22	T3-22	T4-22
Batch Size	2500 Capsules	2500 Capsules	2500 Capsules
Manufacturing Date	01-2022	01-2022	01-2022

Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm submitted a list of 22 products which were approved with stability data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.Dis.No: 60996/TS/2021 valid till 24/05/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase Order No. IMP-1015 for batch no: OP-VICTR-A1-040/21,DRAP attested vide Dy.no. 18262/2021 DRAP dated 30-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	**1.5.9**	Submit regulatory status of approval of applied formulation by reference regulatory authority by way of routine procedure of market authorisation.
2.	**3.2.S.7**	Submit complete stability data of drug substance till the claimed retest date as per zone IV-a conditions.
3.	**3.2.P.2.2.1**	Justify for not performing the comparative study against the innovator product i.e.Lagevrio capsule 200mg.
4.	**3.2.P.5.4**	Justify for selecting 0.1N HCL as a dissolution medium ,when the drug dissolution behavior was similar in all three dissolution mediums as per the comparative dissolution profile submitted in section 3.2.P.2.2.1.
5.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.
6.	**2.3. R.1.1**	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.

Decision of 324th meeting of Registration Board:

Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**1.5.9**	Submit regulatory status of approval of applied formulation by reference regulatory authority by way of routine procedure of market authorisation.	Firm replied that "The European Medicines Agency (EMA) supports the development of medicines that address unmet medical needs. In the interest of public health, applicants may be granted a conditional marketing authorisation for such medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required. Its use is also intended for a public health emergency (e.g. a pandemic).

			The approval of Lagevrio is a routine procedure considering the pandemic situation".
2.	**3.2.S.7**	Submit complete stability data of drug substance till the claimed retest date as per zone IV-a conditions.	Firm submit the real time stability data of 18 months while the submitted stability summary sheet revealed that the claimed re-test period is till 60 months.
3.	**3.2.P.2.2.1**	Justify for not performing the comparative study against the innovator product i.e. Lagevrio capsule 200mg.	Firm replied that License agreement between Optimus Pharma Pvt Ltd. & Medicine Patent Pool in which MSD grant the rights to sublicense certain Patents in furtherance of its policy of improving access to COVID-19 medicines is **attached as Annex-2**, that's why CDP is performed against the Optimus Product.
4.	**3.2.P.5.4**	Justify for selecting 0.1N HCL as a dissolution medium ,when the drug dissolution behaviour was similar in all three dissolution mediums as per the comparative dissolution profile submitted in section 3.2.P.2.2.1.	Firm replied that "as per US-FDA, "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" which recommends paddle method with 0.1N HCl as dissolution medium, that's why we select 0.1N HCl as dissolution medium." However, the reference guidance document of USFDA does not recommend any specific medium for capsule as depicted from the below statement of said guidelines "*The volume of the dissolution medium is generally 500, 900, or 1000 mL. Sink conditions are desirable but not mandatory. An aqueous medium with pH range 1.2 to 6.8 (ionic strength of buffers the same as in USP) should be used. To simulate intestinal fluid (SIF), a dissolution medium of pH 6.8 should be employed. A higher pH should be justified on a case-by-case basis and, in general, should not exceed pH 8.0. To simulate gastric fluid (SGF), a dissolution medium of pH 1.2 should be employed without enzymes. The need for enzymes in SGF and SIF should be evaluated on a case-by-case basis and should be justified. Recent experience with gelatin capsule products indicates the possible need for enzymes (pepsin with SGF and pancreatin with SIF) to dissolve pellicles, if formed, to permit the dissolution of the drug."*
5.	**3.2.P.8**	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submit the updated stability data of drug product i.e. of 6 months.
6.	**2.3. R.1.1**	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which	Submitted

		stability studies data is provided in Module 3 section 3.2. P.8.	

Decision: Deferred for regulatory status of approval of applied formulation by reference regulatory authority by way of routine procedure of market authorization.

965.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta	
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy.no. 2524 dated 26-01-2022	
	Details of fee submitted	PKR 75,000/-:	dated 10/12/2021
	The proposed proprietary name / brand name	**Canrec AM 8mg+2.5mg Tablet**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Candesartan Cilexetil…...8mg Amlodipine Besilate, BP eq. to Amlodipine…...2.5mg	
	Pharmaceutical form of applied drug	Off White, Round Biconvex Tablets having break line on side and other side plain.	
	Pharmacotherapeutic Group of (API)	Candesartan belongs to a class of drugs called angiotensin receptor blockers (ARBs) Amlodipine belongs to a class of drugs called calcium channel blockers	
	Reference to Finished product specifications	Specifications as per Innovator's product.	
	Proposed Pack size	As per DPC	
	Proposed unit price	As per SRO	
	The status in reference regulatory authorities	Product Name: Unisia Combination Tablets LD 8mg+ 2.5mg RRA: Pharmaceuticals and Medical Devices Agency (PMDA) Japan	
	For generic drugs (me-too status)	Not Applicable	
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.	
	Name and address of API manufacturer.	**Candesartan:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd.-Xunqiao site Xuqiao, Linhai, Zhejiang 317024, China. **Amlodipine:** M/s Prudence Pharmachem, Gujarat (India)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,	

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm 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: **(Candesartan Cilexetil)** Real time: 30˚C ± 2˚C / 75% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 5258-12-208,5258-12-209,5258-12-210 Stability study conditions: **(Amlodipine Besylate)** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:AMB/002/01/14,AMB/003/02/14,AMB/004/02/14
	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 Unisia Tablet 8mg + 2.5mg Tablet (Innovator product) PMDA Japan by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is Innovator product Unisia Tablet 8mg + 2.5mg Tablet (Innovator product) PMDA Japan, Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Candesartan:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd.-Xunqiao site Xuqiao, Linhai, Zhejiang 317024, China. **Amlodipine:** M/s Prudence Pharma chem, Gujarat (India)		
API Lot No.	**Candesartan:** 5668-19-508 **Amlodipine:** AMB/111/05/20		
Description of Pack (Container closure system)	Aluminium and Cold forming foil (CFF) which are sealed together and packed in Unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03

Batch Size	10000 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Zhejiang Huahai Pharmaceutical Co. Ltd China:** GMP Certificate No 201907047 issued by CFDA valid till 15-1-2023. **M/s Prudence Pharmachem:** GMP Certificate No S-GMP & GLP/22053332 issued by Food & Drug Control Administration Gujrat India valid till 26-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**M/s Zhejiang Huahai Pharmaceutical Co. Ltd China:** ADC Invoice No: HH20201167, 03-June-2020 is submitted wherein the permission to import API (Candesartan) for the purpose of test/analysis and stability studies is granted. **M/s Prudence Pharmachem:** ADC Invoice No: PPC/030/20-21, 30-May-2020 is submitted wherein the permission to import API (Amlodipine) for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	**Sections**	**Observations/Deficiencies/ Short-comings**	**Response of the Firm**
1.	**3.2.S.4.2 (Candesartan Cilexetil)**	Analytical procedure given in section 3.2.S.4.2 exhibited the assay method via HPLC while the assay method which has verified in section 3.2.S.4.3 performed via titration method, clarification is required in this regard.	Firm replied that, to address above mentioned query, we have revised the analytical procedure of Candesartan Cilexetil as per USP monograph and method verification has also been performed accordingly via HPLC
2.	**3.2.P.1**	Composition of applied product submitted in respective section is not qualitatively similar to the composition of innovator product, so, in this case please submit the compatibility study of active with the excipients.	Submitted
3.	**3.2.P.1**	Justify the quantity of amlodipine besylate used in the composition of applied product i.e. 7mg comparing the quantity mentioned in the	Firm replied that amlodipine besylate 6.93mg is equivalent to about 5mg of amlodipine as per innovator product. The

		composition of reference product i.e.6.93mg.	concentration of API 7mg is used in master formulation as 6.93 values are rounded off to 7mg.
4.	**3.2.P.2.2.1**	Justify for not performing all the quality test mentioned in specification of finished product while establishing the pharmaceutical against reference product.	Firm replied that Only significant quality tests including assay and dissolution were performed for establishing pharmaceutical equivalence. Other less critical tests including disintegration and average weight tests were not performed at this stage.
5.	**3.2.P.5.1**	Justify for not including loss on drying/water determination test in the specification of finished product.	Firm replied that "As loss on drying/water determination is not included in USP monographs of both Candesartan Cilexetil Tablets and Amlodipine Tablets and proposed packing of product is alu-alu blister , therefore, these tests not included in the specification of finished product".
6.	**3.2.P.5.2**	Scientific justification for setting the UV detector limit at 238nm, since the USP recommended the UV detection limit at 282nm for candesartan cilexetil both in individual and in combination product.	Firm replied that "With respect to selection of 238nm wavelength, please note that combination product having candesartan and Amlodipine is not present in USP, therefore, if we followed individual monographs of Candesartan and Amlodipine product as per USP monograph, we need to perform testing for both API is using different HPLC procedures which was more time consuming. To resolve this Issue, we followed a research article to develop and validate the analytical procedure for simultaneous determination of candesartan and Amlodipine via HPLC using 238nm wavelength".
7.	**3.2.P.5.2**	Justify the selection of Buffer pH 6.8 medium for dissolution from the international literature and pharmacoepial reference, further provide the percentile quantity of polysorbate 80 used in the dissolution medium.	Firm replied that "Preparation of buffer solution for dissolution test has been taken form USP monograph of candesartan Cilexetil Tablets and polysorbate 20 is used as per USP monograph which is mentioned in provided finished product testing method. However, as this product is a non-pharmacopeial product and according to CDP study against comparator product, dissolution results found comparable with comparator product in pH 6.8 buffer, therefore, we selected pH 6.8 for release testing as well".
8.	**3.2.P.8**	Justify for using different method for preparation of sample solution as evident from the raw data sheet from that specified in analytical	Firm replied that "Deviation from specified analytical procedure only observed in initial testing of product because at this stage

		procedure given in section 3.2. P.5.2.	method has been developed and under review if required any improvement. Once method has been finalized including method of preparation of sample solution, no deviation was observed from 3rd. month stability data".
9.	**3.2.P.8**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
10.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision of 324th meeting of Registration Board:

Deferred for submission of scientific justification for:

- Applying different analytical procedure for the drug substance of "Candesartan cilexetil" analysis than that recommended by the USP monograph.
- Applied wavelength for Assay analysis of drug product in deviation to that recommended by pharmacopoeial monographs for candesartan cilexetil formulations.

Response of the Firm:

Applying different analytical procedure for the drug substance of "Candesartan cilexetil" analysis than that recommended by the USP monograph.

Firm replied that they have re-evaluated their method and revised it according to the current Candesartan cilexetil monograph of USP and a revised analytical procedure and verification report submitted accordingly.

Applied wavelength for Assay analysis of drug product in deviation to that recommended by pharmacopoeial monographs for candesartan cilexetil formulations.

Firm replied that "With respect to selection of 238nm wavelength, the combination of Amlodipine and candesartan cilexetil is not present in USP pharmacopeia, therefore if we allow individual monographs of candesartan and amlodipine products as per USP monograph, we need to perform testing for both APIs using different HPLC procedures. To resolve this issue, we followed a research article to develop and validate the analytical procedure for simultaneous determination of candesartan and amlodipine via HPLC using 238nm wavelength and according to this peaks of both APIs are well separated and no issue in quantification of both APIs.

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.

966.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta	
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, 7-Jail Road, Quetta	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy.no.2525 dated 26-01-2022	
	Details of fee submitted	PKR 75,000/-:	dated 10/12/2021
	The proposed proprietary name / brand name	**Canrec AM 8mg+5mg Tablet**	

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Candesartan Cilexetil…...8mg Amlodipine Besilate, BP eq to Amlodipine…...5mg
	Pharmaceutical form of applied drug	Off white, Round Biconvex tablets having break line on one side and other side plain
	Pharmacotherapeutic Group of (API)	Candesartan belongs to a class of drugs called angiotensin receptor blockers (ARBs) Amlodipine belongs to a class of drugs called calcium channel blockers
	Reference to Finished product specifications	Specifications as per Innovator's product.
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product Name: Unisia Combination Tablets LD 8mg+ 5mg RRA: Pharmaceuticals and Medical Devices Agency (PMDA) Japan Approved in Austria (Candeblo/Amlo 8mg/5mg Table)
	For generic drugs (me-too status)	Not Applicable
	GMP status of the Finished product manufacturer	Certificate No:015/2021-DRAP (Q)/K issued on 10th September 2021 Tablet (General & Psychotropic), Capsule (General), Oral Liquid Syrup (General), Sterile Liquid Injection/Ampoule, Ointment/Cream, Dry Powder Sachet (General), Dry Powder Suspension (General) section approved.
	Name and address of API manufacturer.	**Candesartan:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd.-Xunqiao site Xuqiao, Linhai, Zhejiang 317024, China. **Amlodipine:** M/s Prudence Pharmachem, Gujarat (India)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm 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: **(Candesartan Cilexetil)** Real time: 30°C ± 2°C / 75% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 5258-12-208,5258-12-209,5258-12-210 Stability study conditions: **(Amlodipine Besylate)** Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: AMB/002/01/14,AMB/003/02/14,AMB/004/02/14

	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 Unisia Tablet 8mg + 5mg Tablet (Innovator product) PMDA Japan by performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is Innovator product Unisia Tablet 8mg + 5mg Tablet (Innovator product) PMDA Japan, Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Candesartan:** M/s Zhejiang Huahai Pharmaceutical Co., Ltd.-Xunqiao site Xuqiao, Linhai, Zhejiang 317024, China. **Amlodipine:** M/s Prudence Pharmachem, Gujarat (India)		
API Lot No.	**Candesartan:** 5668-19-508 **Amlodipine:** AMB/111/05/20		
Description of Pack (Container closure system)	Aluminum and Cold forming foil (CFF) which are sealed together and packed in Unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	10000 Tablets	10000 Tablets	10000 Tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**M/s Zhejiang Huahai Pharmaceutical Co. Ltd China:** GMP Certificate No 201907047 issued by CFDA valid till 15-1-2023 **M/s Prudence Pharmachem:** GMP Certificate No S-GMP & GLP/22053332 issued by Food & Drug Control Administration Gujrat India valid till 26-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**M/s Zhejiang Huahai Pharmaceutical Co. Ltd China:** ADC Invoice No: HH20201167, 03-June-2020 is submitted wherein the permission to import API (Candesartan) for the purpose of test/analysis and stability studies is granted. **M/s Prudence Pharmachem:** ADC Invoice No: PPC/030/20-21, 30-May-2020 is submitted wherein the

		permission to import API (Amlodipine) for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	**Sections**	**Observations/Deficiencies/ Short-comings**	**Response of the Firm**
1.	**3.2.S.4.2 (Candesartan Cilexetil)**	Analytical procedure given in section 3.2.S.4.2 exhibited the assay method via HPLC while the assay method which has verified in section 3.2.S.4.3 performed via titration method, clarification is required in this regard.	Firm replied that, to address above mentioned query, we have revised the analytical procedure of Candesartan Cilexetil as per USP monograph and method verification has also been performed accordingly via HPLC
2.	**3.2.P.1**	Composition of applied product submitted in respective section is not qualitatively similar to the composition of innovator product, so, in this case please submit the compatibility study of active with the excipients.	Submitted
3.	**3.2.P.1**	Justify the quantity of amlodipine besylate used in the composition of applied product i.e. 7mg comparing the quantity mentioned in the composition of reference product i.e.6.93mg.	Firm replied that amlodipine besylate 6.93mg is equivalent to about 5mg of amlodipine as per innovator product. The concentration of API 7mg is used in master formulation as 6.93 values are rounded off to 7mg.
4.	**3.2.P.2.2.1**	Justify for not performing all the quality test mentioned in specification of finished product while establishing the pharmaceutical against reference product.	Firm replied that Only significant quality tests including assay and dissolution were performed for establishing pharmaceutical equivalence. Other less critical tests including disintegration and average weight tests were not performed at this stage.
5.	**3.2.P.5.1**	Justify for not including loss on drying/water determination test in the specification of finished product.	Firm replied that "As loss on drying/water determination is not included in USP monographs of both Candesartan Cilexetil Tablets and Amlodipine Tablets and proposed packing of product is alu-alu blister , therefore, these tests not included in the specification of finished product".
6.	**3.2.P.5.2**	Scientific justification for setting the UV detector limit at 238nm, since the USP recommended the UV detection limit at 282nm for candesartan cilexetil both in individual and in combination product.	Firm replied that "With respect to selection of 238nm wavelength, please note that combination product having candesartan and Amlodipine is not present in USP, therefore, if we followed individual monographs of Candesartan and Amlodipine product as per USP

			monograph, we need to perform testing for both API is using different HPLC procedures which was more time consuming. To resolve this Issue, we followed a research article to develop and validate the analytical procedure for simultaneous determination of candesartan and Amlodipine via HPLC using 238nm wavelength".
7.	**3.2.P.5.2**	Justify the selection of Buffer pH 6.8 medium for dissolution from the international literature and pharmacoepial reference, further provide the percentile quantity of polysorbate 80 used in the dissolution medium.	Firm replied that "Preparation of buffer solution for dissolution test has been taken form USP monograph of candesartan Cilexetil Tablets and polysorbate 20 is used as per USP monograph which is mentioned in provided finished product testing method. However, as this product is a non-pharmacopeial product and according to CDP study against comparator product, dissolution results found comparable with comparator product in pH 6.8 buffer, therefore, we selected pH 6.8 for release testing as well".
8.	**3.2.P.8**	Justify for using different method for preparation of sample solution as evident from the raw data sheet from that specified in analytical procedure given in section 3.2. P.5.2.	Firm replied that "Deviation from specified analytical procedure only observed in initial testing of product because at this stage method has been developed and under review if required any improvement. Once method has been finalized including method of preparation of sample solution, no deviation was observed from 3rd. month stability data".
9.	**3.2.P.8**	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
10.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision of 324th meeting of Registration Board:

Deferred for submission of scientific justification for:

- Applying different analytical procedure for the drug substance of "Candesartan cilexetil" analysis than that recommended by the USP monograph.
- Applied wavelength for Assay analysis of drug product in deviation to that recommended by pharmacopoeial monographs for Candesartan cilexetil formulations.

Response of the Firm:

Applying different analytical procedure for the drug substance of "Candesartan cilexetil" analysis than that recommended by the USP monograph.

Firm replied that they have re-evaluated their method and revised it according to the current Candesartan cilexetil monograph of USP and a revised analytical procedure and verification report submitted accordingly.

Applied wavelength for Assay analysis of drug product in deviation to that recommended by pharmacopoeial monographs for candesartan cilexetil formulations.

Firm replied that "With respect to selection of 238nm wavelength, the combination of Amlodipine and candesartan cilexetil is not present in USP pharmacopeia, therefore if we allow individual monographs of candesartan and amlodipine products as per USP monograph, we need to perform testing for both APIs using different HPLC procedures. To resolve this issue, we followed a research article to develop and validate the analytical procedure for simultaneous determination of candesartan and amlodipine via HPLC

using 238nm wavelength and according to this peaks of both APIs are well separated and no issue in quantification of both APIs.
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.**

Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

967.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Private Limited, Plot No 62 Quaid e Azam Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s CCL Pharma Private Limited, Plot No 62 Quaid e Azam Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.19741 dated 06/07/2022
	Details of fee submitted	PKR 75,000/-: dated 23/06/2022
	The proposed proprietary name / brand name	**Eluxa Tablet 75mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Eluxadoline …….....75mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-propulsive / Mixed mu opioid receptor agonist/delta opioid receptor antagonist Eluxadoline is a mu-opioid receptor agonist; eluxadoline is also a delta opioid receptor antagonist and a kappa opioid receptor agonist
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	5's, 10's, l4's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Viberzi Tablet by M/s Allergan Holdings USA. (USFDA Approved)
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	DML renewal Inspection conducted on 14.09.2020, 15.09.2020 and 21.10.2020. New DML granted on 08.06.2021 with effect from 21.07.2020. Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid) approved. Ref. letter no. 819 4 /2022-DRAP (Addl.Dire) dated 07.07.2022 The Firm has applied for GMP Inspection. The application is under processes at DRAP Office and inspection will be done as per

		availability of Area FID. The firm's last GMP status is Compliant / Good.
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceutical Co., Limited Address: No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Eluxadoline is not present in Pharamcopoeia. 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 (12 month) Accelerated: 40°C ± 2°C / 75% ± 5%RH (6 month) Batches: (20180101, 20180102, 20180201)
	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 innovator Viberzi tablet 75mg (Batch no. 3180416, EXP date: Sep-22) manufactured by M/s Allergen Holdings, USA by performing quality tests (Identification, Assay, Dissolution etc.) CDP has been performed against the same brand that is Viberzi tablet 75mg manufactured by M/s Allergen Holdings, USA in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co., Limited		
API Lot No.	ELD-202107001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (4×7'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, 9, 12 (Months)		
Batch No.	T2-22	T3-22	T4-22

Batch Size	1000 Tab	1000 Tab	1000 Tab
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the list of products previously approved with stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate of M/s. JIANGSU YONGAN PHARMACEUTICAL Co. Ltd. issued by Huai'an Pharmaceutical Industry Association, valid till 14/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice having diary No.12869/2021/DRAP dated 27/08/2021 is submitted wherein the permission to import of API is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.4	Justify for not including the test of particle size (laser diffraction) and steroisomeric purity (Chiral HPLC) in the release specification of drug substance since these tests are included in the specification of drug substance by innovator brand.	As per FDA chemistry review, particle size is not included in the drug substance specification. For purity, Drug substance and Drug product manufacturer have performed Assay by HPLC and Impurites testing for ensuring the quality. However, in the public assessment report of EMA approved innovator brand both of these test is included in the release specification of drug substance. Further, the drug substance used in applied formulation is different from the drug substance of innovator brand as evident from the chemical structure given in section 3.2.S.1.
2.	3.2.S.4.4	According drug substance documents α polymorphic form of drug substance is supplied by drug substance manufacturer while the review literature of innovator products reveal that Polymorphic form-I is the only non-solvated, crystalline form of the active substance which has been used in the formulation of innovator product, clarification is required either the Form α is similar to	Firm replied that "It is the same form, only notation is different i.e., Form 1 or Form Alpha".

		polymorphic Form-I of eluxadoline.	
3.	3.2.P.2.2.1	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.	Submitted
4.	3.2.S.7	Justify for not including water content, stereoisomeric purity in the shelf life specification of the drug substance, since these tests are included in the shelf life specification of drug substance of innovator brand.	Firm replied that The API manufacturer (Vendor) claims that loss on drying test was run to determine the water content, in line with the instructions provided in the drug master file. For purity, Drug substance and Drug product manufacturer have performed Assay by HPLC and Impurites testing for ensuring the quality. Impurities testing mentioned in the stability data is not related to the chiral impurity testing of drug substance.
5.	3.2.S.7	Provide complete stability data of drug substance performed at both accelerated and long term condition till the claimed re-test date, since you have submitted real time data of only 12 month time period.	Submitted
6.	3.2.P.8	Justify for not including the test of water content and chiral purity in the shelf life specification of drug product ,since both of these critical test are included in the shelf life specification of innovator product.	As per US-FDA chemistry review, Life cycle management, these tests are not included in the Critical Quality Attributes. However, the tests are the part of shelf life specification of innovator brand as per the review literature.

Indication:
VIBERZI is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D).
DOSAGE AND ADMINISTRATION
The recommended dosage in adults is 100 mg twice daily taken with food.
The recommended dosage is 75 mg twice daily taken with food in patients
who do not have a gallbladder
are unable to tolerate the 100 mg dose
are receiving concomitant OATP1B1 inhibitors
have mild or moderate hepatic impairment
Discontinue VIBERZI in patients who develop severe constipation for more than 4 days.
If a dose is missed, take the next dose at the regular time; do not take 2 doses at once.

Decision of 324th meeting of Registration Board:
Deferred for scientific justification for following along with documented evidence:

- Variation of the chemical structure of the drug substance, as evident from section 3.2.S.1, from that of the innovator.
- According drug substance documents α polymorphic form of drug substance is supplied by drug substance manufacturer while the review literature of innovator products reveal that Polymorphic form-I is the only non-solvated, crystalline form of the active substance which has been used in the formulation of innovator product, clarification is required either the Form α is similar to polymorphic Form-I of Eluxadoline.

Response of the Firm:
Variation of the chemical structure of the drug substance, as evident from section 3.2.S.1, from that of the innovator.

Firm submitted the declaration from API Manufacturer in which they declare that they manufactured Eluxadoline Form-I same as innovator and specify the chemical structure which is similar to innovator brand.
However, the firm did not submit any clarification/correct document regarding the chemical structure previously submitted in section 3.2.S. which was similar to innovator product.
Full chemical name mentioned in the review literature of innovator product:
5-[[[(2S)-2-amino-3- [4-(amino carbonyl)-2,6-dimethylphenyl]-1- oxopropyl] [(1S)-1-(4-phenyl-1H-imidazol-2-yl) ethyl] amino] methyl]-2-methoxybenzoic acid.
Full chemical name mentioned in the section 3.2.S.1 section of previously submitted dossier:
5-[[[(2S)-2-amino-3- [4-(amino carbonyl)-2,6-dimethylphenyl]-1- oxopropyl] [(1S)-1-(5-phenyl-1H-imidazol-2-yl) ethyl] amino] methyl]-2-methoxybenzoic acid.

According drug substance documents α polymorphic form of drug substance is supplied by drug substance manufacturer while the review literature of innovator products reveals that Polymorphic Form-I is the only non-solvated, crystalline form of the active substance which has been used in the formulation of innovator product, clarification is required either the Form α is similar to polymorphic Form-I of Eluxadoline.
Firm replied that API manufacturer declared that "they undertake that polymorphic form α is form I only the notation is different, in China they write form I as form α.

Decision: Deferred for submission of open part of Drug Master File from API Manufacturer which confirms the chemical name and structure of drug substance.

968.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharma Private Limited, Plot No 62 Quaid e Azam Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s CCL Pharma Private Limited, Plot No 62 Quaid e Azam Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.19742 dated 06/07/2022
	Details of fee submitted	PKR 75,000/-: vide slip no. 8459056839 dated 23/06/2022
	The proposed proprietary name / brand name	Eluxa Tablet 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Eluxadoline …….....100mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-propulsive / Mixed mu opioid receptor agonist/delta opioid receptor antagonist Eluxadoline is a mu-opioid receptor agonist; eluxadoline is also a delta opioid receptor antagonist and a kappa opioid receptor agonist
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	5's, 10's, l4's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Viberzi Tablet by M/s Allergan Holdings USA. (USFDA Approved)
	For generic drugs (me-too status)	NA

	GMP status of the Finished product manufacturer	DML renewal Inspection conducted on 14.09.2020, 15.09.2020 and 21.10.2020. New DML granted on 08.06.2021 with effect from 21.07.2020. Tablet (General), Capsule (General), Oral Liquid, Dry Powder Suspension, Liquid Injectable & Capsule section (Steroid) approved. Ref. letter no. 819 4 /2022-DRAP (Addl.Dire) dated 07.07.2022 The Firm has applied for GMP Inspection. The application is under processes at DRAP Office and inspection will be done as per availability of Area FID. The firm's last GMP status is Compliant / Good.
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceutical Co., Limited Address: No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Eluxadoline is not present in any Pharmacopoeias. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH (12 month) Accelerated: 40°C ± 2°C / 75% ± 5%RH (6 month) Batches: (20180101, 20180102, 20180201)
	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 innovator Viberzi tablet 100mg manufactured by M/s Allergan Holdings, USA (Batch no. 3195885 expiry date: Jan-2024) by performing quality tests (Identification, Assay, Dissolution) CDP has been performed against the same brand that is Viberzi tablet 100mg manufactured by M/s Allergan Holdings, USA in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co., Limited	

API Lot No.	ELD-202107001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (4×7'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, 9, 12 (Months)		
Batch No.	T2-22	T3-22	T4-22
Batch Size	1000 Tab	1000 Tab	1000 Tab
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the list of products previously approved with stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate of M/s. JIANGSU YONGAN PHARMACEUTICAL Co. Ltd. issued by Huai'an Pharmaceutical Industry Association, valid till 14/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice having diary No.12869/2021/DRAP dated 27/08/2021 is submitted wherein the permission to import of API is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.4	Justify for not including the test of particle size (laser diffraction) and steroisomeric purity (Chiral HPLC) in the release specification of drug substance since these tests are included in the specification of drug substance by innovator brand.	As per FDA chemistry review, particle size is not included in the drug substance specification. For purity, Drug substance and Drug product manufacturer have performed Assay by HPLC and Impurities testing for ensuring the quality. However, in the public assessment report of EMA approved innovator brand both of these tests are included in the release specification of drug substance. Further, the drug substance used in applied formulation is different from the drug substance of innovator brand as evident from the chemical structure given in section 3.2.S.1.

2.	3.2.S.4.4	According drug substance documents α polymorphic form of drug substance is supplied by drug substance manufacturer while the review literature of innovator products reveal that Polymorphic form-I is the only non-solvated, crystalline form of the active substance which has been used in the formulation of innovator product, clarification is required either the Form α is similar to polymorphic Form-I of eluxadoline.	Firm replied that "It is the same form, only notation is different i.e., Form 1 or Form Alpha".
3.	3.2.P.2.2.1	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.	Submitted
4.	3.2.S.7	Justify for not including water content, stereo isomeric purity in the shelf life specification of the drug substance, since these tests are included in the shelf life specification of drug substance of innovator brand.	Firm replied that The API manufacturer (Vendor) claims that loss on drying test was run to determine the water content, in line with the instructions provided in the drug master file. For purity, Drug substance and Drug product manufacturer have performed Assay by HPLC and Impurities testing for ensuring the quality. Impurities testing mentioned in the stability data is not related to the chiral impurity testing of drug substance.
5.	3.2.S.7	Provide complete stability data of drug substance performed at both accelerated and long term condition till the claimed re-test date, since you have submitted real time data of only 12 month time period.	Submitted
6.	3.2.P.8	Justify for not including the test of water content and chiral purity in the shelf life specification of drug product ,since both of these critical test are included in the shelf life specification of innovator product.	As per US-FDA chemistry review, Life cycle management, these tests are not included in the Critical Quality Attributes. However, the tests are the part of shelf life specification of innovator brand as per the review literature.

Decision of 324th meeting of Registration Board:

Deferred for scientific justification for following along with documented evidence:

- Variation of the chemical structure of the drug substance, as evident from section 3.2.S.1, from that of the innovator.
- According to drug substance documents α polymorphic form of drug substance is supplied by drug substance manufacturer while the review literature of innovator products reveal that Polymorphic form-I is the only non-solvated, crystalline form of the active substance which has been used in the formulation of innovator product, clarification is required either the Form α is similar to polymorphic Form-I of Eluxadoline.

Response of the Firm:

Variation of the chemical structure of the drug substance, as evident from section 3.2.S.1, from that of the innovator.

Firm submitted the declaration from API Manufacturer in which they declare that they manufactured Eluxadoline Form-I same as innovator and specify the chemical structure which is similar to innovator brand.
However, the firm did not submit any clarification/correct document regarding the chemical structure previously submitted in section 3.2.S. which was similar to innovator product.
Full chemical name mentioned in the review literature of innovator product:
5-[[[(2S)-2-amino-3- [4-(amino carbonyl)-2,6-dimethylphenyl]-1- oxopropyl] [(1S)-1-(4-phenyl-1H-imidazol-2-yl) ethyl] amino] methyl]-2-methoxybenzoic acid.
Full chemical name mentioned in the section 3.2.S.1 section of previously submitted dossier:
5-[[[(2S)-2-amino-3- [4-(amino carbonyl)-2,6-dimethylphenyl]-1- oxopropyl] [(1S)-1-(5-phenyl-1H-imidazol-2-yl) ethyl] amino] methyl]-2-methoxybenzoic acid.

According drug substance documents α polymorphic form of drug substance is supplied by drug substance manufacturer while the review literature of innovator products reveals that Polymorphic Form-I is the only non-solvated, crystalline form of the active substance which has been used in the formulation of innovator product, clarification is required either the Form α is similar to polymorphic Form-I of Eluxadoline.
Firm replied that API manufacturer declared that "they undertake that polymorphic form α is form I only the notation is different, in China they write form I as form α.

Decision: Deferred for submission of open part of Drug Master File from API Manufacturer which confirms the chemical name and structure of drug substance.

Agenda of Evaluator PEC-XX

A) Registration applications of newly granted DML or New section (Human)

New DML:

1) M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat Islamabad, CLB in its 278th meeting held on 10th and 11th December 2020, has considered and approved the grant of DML with following three sections:

- **Tablet (General) section.**
- **Capsule (General) section.**
- **Dry Powder Suspension (General) section.**
- **Sachet (General) section.**
- **Ampoule (General) section.**

969.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33964 dated 24/11/2022
	Details of fee submitted	PKR 30,000/- dated 21/11/2022
	The proposed proprietary name / brand name	**Caremont 10 mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Montelukast as sodium……10 mg

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Accord Healthcare Limited United Kingdom **MHRA** Approved
	For generic drugs (me-too status)	M/s Sami Pharma **Brand Name & Strength**: Montika 10mg Film coated Tablet **Registration Number**: 035561.
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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 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 impurities & related substances (specified & unspecified), analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against **Montika 10 mg Tablet** by SAMI Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)		
API Lot No.	MKS/2107023		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
13.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.DIS.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 DATE 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required.

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): **2.3.S.3.1& 3.2.S.3** Elucidation of Structure and other Characteristics of Drug Substance has not been Provided. **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.S.4** Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer. **3.2.P.2** Batch no of innovator product and test product has not been mentioned under CDP. **3.2.P.8** Documents for the procurement of API (approval from DRAP) to be submitted. **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports is not submitted		
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.		
970.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.33969 dated 24/11/2022
	Details of fee submitted	PKR 30,000/- dated 21/11/2022
	The proposed proprietary name / brand name	**Caremont 4 mg chewable tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable tablet contains: Montelukast as sodium……4 mg
	Pharmaceutical form of applied drug	Chewable tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Accord Healthcare Limited United Kingdom **MHRA** approved
	For generic drugs (me-too status)	M/s Sami Pharma Montika 4mg chewable Tablet Registration Number: 035560
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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 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 impurities & related substances (specified & unspecified), analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against **Montika 4 mg Tablet** by SAMI Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)		
API Lot No.	MKS/2107023		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.DIS.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 Date 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required
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):
2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.
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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.
3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

971.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.37335 dated 21/12/2022
	Details of fee submitted	PKR 30,000/- dated 07/12/2022
	The proposed proprietary name / brand name	**Caremont 4 mg sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Montelukast as sodium……..4 mg
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merck Sharp & Dohme Limited Singulair® Paediatric 4 mg Granules **MHRA** Approved
	For generic drugs (me-too status)	M/s Getz Pharma Montget 4mg powder sachet **Registration Number**: 044046
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Sachet (General) section was approved.

	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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 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 impurities & related substances (specified & unspecified), analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against **Montiget 4mg Sachet** by M/s Getz Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)		
API Lot No.	MKS/2107023		
Description of Pack (Container closure system)	Aluminium foil sheet (14's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 sachet	100 sachet	100 sachet
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.Dis.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 Date 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required.
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):

2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.

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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.

3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

972.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 40 dated 02/01/2023
	Details of fee submitted	PKR 30,000/- dated 21/112022
	The proposed proprietary name / brand name	**CARA-D3 5mg/1ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Cholecalciferol……..5 mg
	Pharmaceutical form of applied drug	Sterile solution for I.M & Oral
	Pharmacotherapeutic Group of (API)	Vitamin D analog
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VITAMIN D3 GOOD INJECTION **Doucharl-Recodrati-ANSM (France) approved.**
	For generic drugs (me-too status)	D DROP Inj by Ipram Pharmaceuticals Reg No 052799
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Ampoule (General) section is approved.
	Name and address of API manufacturer.	ZHEJIANG NHU COMPANY LTD. Address: Plot # 428 Xinchang Dadao West Road, Qixing Street, Xinchang Ciunty, Zhejjiang Provance, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, 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 cholecalciferol (drug substance) 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 related substances, 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: 200902181A 200902171A 200902161A
	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 study performed against comparator product. Quality parameters studied were appearance, identification, sterility, Endotoxin and Assay were studied.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	ZHEJIANG NHU COMPANY LTD. Address: Plot # 428 Xinchang Dadao West Road, Qixing Street, Xinchang Ciunty, Zhejjiang Provance, China		
API Lot No.	Not provided		
Description of Pack (Container closure system)	USP Type 1 glass ampoule, packed in Unit Carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	2000 ampoule	2000 ampoule	2000 ampoule
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-2022	05-2022	05-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. ZJ20180077 dated 24.07.2018 issued by China Food and Drug Administration valid till 23/07/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No F2020442 Dated 17.12.2020 confirming import of Vitamin D3 40MIU 3kg Batch No 01201203VD **in the name of M/s Amaan pharma,** Lahore. Approved from DRAP Lahore dated 05.01.2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor:

Excipient/diluent used in formulation was Crodamol oil (medium chain triglyceride) as per innovator product.

Sterilization was performed via membrane filtration (0.2 µm)

Observations:

Sr.#	Observation	Reply	Remarks
1.	The applied finished product specification is USP while instant formulation is not available in USP/BP or any other official monograph**.** Applied formulation to be corrected "as per innovator specification" along with fee (Rs 7500/-)	Finished product of applied formulation has been corrected "as per innovator specification" along with fee (Rs 7500/-) dated 07.03.2023.	Complied
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided.	Analytical Method Verification studies have been provided by Drug Product manufacturer	Complied
3.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Detailed analytical procedures for the testing of drug substance provided by Drug product manufacturer.	Complied
4.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability	CoA of Drug Substance has been provided from both DS manufacturer as well as Drug product manufacturer Batch No **01201203VD**	Complied

	studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.		
5.	Stability data of Drug substance submitted with conditions such as: Real time: 5˚C ± 3˚**C** for 36 months Accelerated: 25˚C ± 2˚C / 60% ± 5%RH for 6 months The above mentioned conditions need to be justified or submit data as per zone IV-A**.**	Not provided Stability data for all three batches 200902181A, 200902171A and 200902161A has to be provided as per zone IV-A**.** Or Justify the conditions that have been mentioned.	Storage condition of Cholecalciferol has been verified from BP (2022) wherein refrigerated condition has been mentioned. Hence stability condition is justified.
6.	Batch no of innovator product and test product has not been mentioned under pharmaceutical equivalence study.	Not provided	Not complied
7.	Documents for the procurement of API submitted wherein name of firm was mentioned as **M/s Amaan pharma, Lahore.** Clarify it or submit loan agreement for purchase of API from M/s Amaan pharma, Lahore.	Loan agreement for purchase of API from M/s Amaan pharma, Lahore has been submitted dated 09.04.2022.	Complied
8.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied

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.**
- **Before issuance of registration letter firm shall submit Batch no of innovator product and test product used for performing pharmaceutical equivalence study.**

973.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 41 dated 02/01/2023
	Details of fee submitted	PKR 30,000/-: dated 07/12/2022

	The proposed proprietary name / brand name	**Cobal injection 500mcg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1 ml ampoule contains: Mecobalamin…….500mcg
	Pharmaceutical form of applied drug	Sterile solution for I.V/I.M use
	Pharmacotherapeutic Group of (API)	B03BA05 - Mecobalamin ; Belongs to the class of Vitamin B12 (cyanocobalamin and analogues).
	Reference to Finished product specifications	BP
	Proposed Pack size	10's , 5s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal Injection PMDA (Japan) approved
	For generic drugs (me-too status)	**Brand Name & Strength**: Methycobal (by Hilton pharma Karachi) 500mcg/ml **Registration Number**: 010313.
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Ampoule (General) section is approved.
	Name and address of API manufacturer.	M/s Mahima Lifesciences (Pvt) Ltd B.S.T road , Ganaur District Sonepat, Haryana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Mecobalamin (Drug substance) is present in JP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities (individual and total), 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: MLMCB-361113 MLMCB-381113 MLMCB-391213
	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 Methycobal 500mcg/ml injection by M/s Hilton pharma karachi (Batch No 143800). Quality parameters studied were appearance, identification, sterility, Endotoxin, pH and Assay were studied.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Mahima Lifesciences (Pvt) Ltd B.S.T road , Ganaur District Sonepat, Haryana, India		
API Lot No.	Not provided		
Description of Pack (Container closure system)	USP Type 1 glass ampoule, packed in Unit Carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	2500 ampoules	2500 ampoules	2500 ampoules
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		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 12/55-2 Drugs1-2020/7030 dated 26.10.2020 issued by Food and Drug Administration, Haryana Panchkula **valid till 12/09/2022.**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
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):		

- Excipient/diluent used in formulation was Mannitol, EDTA and WFI.
- Sterilization was performed via membrane filtration (0.2 µm). Since Mecobalamin is light and heat sensitive therefore terminal sterilization was not opted.
- Column temperature was adopted as constant temperature of about 40◦C (as per JP monograph)

Observations:

Sr.#	Observation	Reply	Remarks
1.	The applied finished product specification is BP while instant formulation is not available in USP/BP or any other official monograph**.** Applied formulation to be corrected "as per innovator specification" along with fee (Rs 7500/-).	Firm has submitted revised/corrected specification "As per innovator's specification" along with fee of Rs 7500/- Dated 08.03.2023	Complied
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies of **Mecobalamin** has been performed including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer	Complied
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Firm has provided CoA of relevant batch No MLMCB-230422 from both Drug Substance and Drug Product manufacturer.	Complied
4.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided	Provided	Complied
5.	Quantity of Drug substance to be justified in Batch formula/Master formula. Quantity per ml mentioned as 0.650mcg Quantity per commercial batch (50,000 ampoules) mentioned as 0.0325Kg Quantity per trial batch (2500 ampoules) mentioned as 0.001625Kg	Quantity of Drug Substance already mentioned in batch formula was typographic error, which has been corrected/revised as follows: Quantity per ml mentioned as 568.18mcg (Potency of mecobalamin taken as 88%) Quantity per trial batch (2500 ampoules) mentioned as 1420.45 g Quantity per commercial batch (50,000 ampoules) mentioned as 28,409 gm	Potency of drug substance taken as 88% is justified on as is basis.
6.	Justification for selection of assay limit as 90-125%. Moreover, variation in assay results during stability	Although assay limit mentioned was wide as 90-125% yet our assay result	Justified

	studies to be justified which found to be increased with time points (Batch No T-01 and T-03)	was according to 100% and will keep limit as 90-110% Moreover slight variation/increase in assay result was due to handling/systematic error, which was not "significant change".	
7.	Compatibility of the Drug Substance(s) with excipient such as EDTA and Mannitol is to be provided otherwise provide reference of excipients used in innovator/reference product	Mannitol has been used in innovator formulation EDTA has been omitted from trial batches practically. The actual formulation didn't contain EDTA	Verified Revised batch formula/master formula to be submitted alongwith prescribed fee
8.	Documents for the procurement of API to be submitted along with approval from DRAP.	Commercial invoice No EXP/53/22-23 dated 18.04.2022 confirming import of 5g mecobalamin batch No MLMCB-230422	Firm has submitted Airway bill as an evidence for import of drug substance.
9.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied

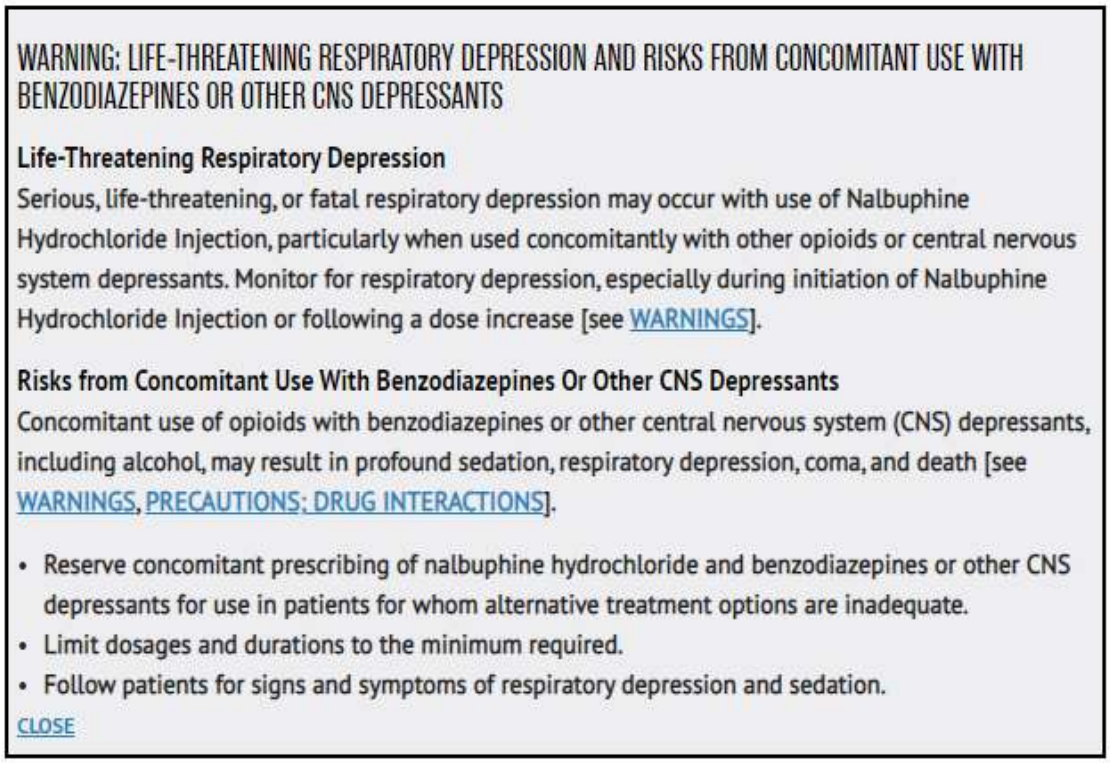
Decision: Approved with Innovator's specifications.

- **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.**

974.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.38001 dated 27/12/2022
	Details of fee submitted	PKR 30,000/-: dated 21/12/2022
	The proposed proprietary name / brand name	**Nubin Injection 10mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Nalbuphine Hydrochloride ……..10mg
	Pharmaceutical form of applied drug	Sterile solution for injection
	Pharmacotherapeutic Group of (API)	Opioid agonist-antagonist..
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nubain Injection USFDA approved
	For generic drugs (me-too status)	Kinz inj . Reg No 018686 By Sami Pharmaceuticals (Pvt) Ltd.
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Ampoule (General) section is approved
	Name and address of API manufacturer.	M/**s** Micro Orgo Chem. Shed No-C 1 B 57, L.I.C sector, G.I.D.C Vapi, Dist, Valsad, Gujrat.
	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 Nalbuphine HCl is not available. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities (individual and total), 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: MO/NBP/1401 MO/NBP/1402 MO/NBP/1403
	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 against Nubain injection by Endo pharmaceutical Inc. (Batch No BB14574). Quality parameters studied were appearance, Average volume and Assay were studied against Test product Batch No NB/I-01

	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** Micro Orgo Chem. Shed No-C 1 B 57, L.I.C sector, G.I.D.C Vapi, Dist, Valsad, Gujrat.		
API Lot No.	MO/NBP/2102		
Description of Pack (Container closure system)	USP Type I glass ampoule		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NB/I-T01	NB/I-T02	NB/I-T03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-2022	05-2022	05-2022
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided	
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 provide clearance certificate from DRAP dated 22.04.2022, confirming import of Nalbuphine HCl 100gm **Batch No MO/NBP/2102**	
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)	Not provided	
Remarks of Assessor (DD PEC-XX: Approved in USFDA with Box warning.			



WARNING: LIFE-THREATENING RESPIRATORY DEPRESSION AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of Nalbuphine Hydrochloride Injection, particularly when used concomitantly with other opioids or central nervous system depressants. Monitor for respiratory depression, especially during initiation of Nalbuphine Hydrochloride Injection or following a dose increase [see WARNINGS].

Risks from Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death [see WARNINGS, PRECAUTIONS; DRUG INTERACTIONS].

- Reserve concomitant prescribing of nalbuphine hydrochloride and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

CLOSE

Terminal sterilization was performed at 121°C for 30min

Observations:

1

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**.**	Firm has submitted copy of GMP certificate No S-GMP & GLP/21092920 valid till 14.09.2023.	Complied
2.	Provide results of analysis of relevant batch(es) of Drug Substance **(Batch No MO/NBP/2102)** 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 / API manufacture	CoA from both Drug Substance and Drug Product manufacturer (**Batch No MO/NBP/2102)** has been submitted.	Complied
3.	Compliance Record of HPLC software 21CFR & audit trail reports and Digital data logger is not submitted	Digital data logger is provided however Compliance Record of HPLC software 21CFR is not provided	Not complied

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.**

975.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 36503 dated 15/12/2022
	Details of fee submitted	PKR 30,000/-: dated 07/12/2022
	The proposed proprietary name / brand name	**Rosucare 10 mg film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin as Rosuvastatin calcium…10 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonist (wrongly mentioned)
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CRESTOR Tablets 10 mg By M/s AstraZeneca Pharmaceutical USA. USFDA Approved
	For generic drugs (me-too status)	Rovista tablets 10mg by M/s Getz Pharma Reg No 044044
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd Block No: 251-252, Sachin Magdalla Road GIDC- Sachin, Dist: -Surat (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)	Official monograph of Rosuvastatin Calcium is available in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for organic impurities, unspecified impurities and total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: SCT/ST/001/2015 SCT/ST/002/2015 SCT/ST/003/2015
	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 and comparative dissolution profile was performed against Rovista 10 mg Tablet by Getz Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 were 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	CTX Lifesciences (P) Ltd Block No: 251-252, Sachin Magdalla Road GIDC- Sachin, Dist: -Surat (Gujrat) India		
API Lot No.	**21RU000026**		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021

Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
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 Invoice No E1/3012100205 Dated 21.06.2021 confirming import of Rosuvastatin calcium 0.25gm Batch No **21RU000026**. Approval from DRAP is required.
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):

1.5.5 Provide correct pharmacotherapeutic group of Drug Substance.

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

2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided

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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 Potency adjustment (salt factor) of Drug substance to be justified in Batch formula i.e 10.4mg of Rosuvastatin calcium eq to 10mg Rosuvastatin, since reference product (MHRA approved) is provided as: *46.36 mg Rosuvastatin calcium eq to 10mg Rosuvastatin.*

3.P.2.1.1 Compatibility of the Drug Substance(s) with excipient (Calcium phosphate) is not provided.

3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.

3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Registration applications of newly granted DML or New section (Human)

New Section:

2) M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar, CLB in its 282nd meeting held on 31st August, 2021, has considered and approved the grant of following additional section/facility:

- **Dry Powder Inhaler Capsule (General) section in place of Sachet (General)-New.**

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 34288 dated 28.11.2022
	Details of fee submitted	PKR 30,000/- dated 10.11.2022
	The proposed proprietary name / brand name	**Combrain 200mcg + 6mcg capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Budesonide……200mcg Formoterol fumarate…..6mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	Corticosteroid and Long acting β_2 adrenergic agonist.
	Reference to Finished product specifications	As per innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Symbicort turbohaler 200mcg + 6mcg inhalation powder MHRA approved
	For generic drugs (me-too status)	Venticort Rota capsule Macter International Reg. No. 081177
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for **three years.** New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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, and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Formoterol fumarate dihydrate** The firm as submitted detail of nomenclature, structure, general properties, solubility, physical

		form, manufacturers, description of manufacturing process and controls, tests for impurity A&F, unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance **Budesonide:** The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,L,D,K & unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Formoterol fumarate dihydrate** Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FF-0071013 M, FF-0010514 and FF-0010515 M) **Budesonide:** Real time: 30˚C ± 2˚C / 75% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(BDS-0071216, BDS-0010415 and BDS-0020514)
	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, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence of Eye Drop dosage form is performed. Moreover comparator product is to be clarified.
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.

STABILITY STUDY DATA	
Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
API Lot No.	Not provided
Description of Pack (Container closure system)	Not provided
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1, 2, 3, 6 (Months)

	Real Time: 0, 3, 6, (Months)		
Batch No.	T-27	T-28	T-29
Batch Size	500 Caps	500 Caps	500 Caps
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	28-11-2021	28-11-2021	28-11-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
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)	Not provided

Remarks of Assessor (DD PEC[XX]):

1) Label claim of RRA approved formulation (Symbicort® Turbohaler® 200 micrograms/6 micrograms/ powder for inhalation) is as follows:

   Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 160 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation.
   Each metered dose contains: budesonide 200 micrograms/inhalation and formoterol fumarate dihydrate 6 micrograms/inhalation.
   Firm has not provided information regarding ***delivered dose***

2) **3.2.P.2** In reference product quantity of Lactose monohydrate used is 730microgram while in applied formulation the quantity of Lactose monohydrate used was 50mg. justify it

3) **3.2.P.2** In reference product Lactose monohydrate is the only excipient been used while firm used other excipients as well such as Talcum powder, Macragol 100, Povidone, Aerosil 200 . justify it, also provide Drug-Excepient compatibility studies of said excipients.
4) **3.2.P.2** The container closure system of reference product, is an inspiratory flow-driven, multidose powder inhaler containing metered doses which is made of different plastic materials, while the applied formulation is primarily pre-dispensed in unit dose hard capsules. Justification shall be submitted for pharmaceutical equivalence of the applied product against the reference product with respect to change in primary container closure system, compatibility of applied formulation with the hard gelatin capsule.
5) **3.2.P.5** Specification of Dug Product did not include water content test which is critical quality parameters for DPI.

6) **3.2.P.2** Pharmaceutical equivalence study to be performed including all quality parameters, Moreover, name batch no and manufacturer of both Test product and Reference product to be provided. 7) **3.2.P.2** Batch formula for proposed commercial batch size should 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. 8) **3.2.P.2** Potency adjustment (salt factor) calculation was not provided for Formoterol fumarate dihydrate in Batch formula. 9) **3.2.P.2** Detailed Analytical testing method of Drug Product to be provided. 10) **3.2.P.2** Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device (name, model, manufacturer and shelf life) provided in pack. 11) **3.2.P.8** Documents for the procurement of API to be submitted. 12) **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted. 13) **3.2.S.4** Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer 14) **3.2.S.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 / API manufacture. 15) **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided 16) **3.2.S.4** CoA of Drug Substance Formoterol fumarate dihydrate particle size distribution test was not performed which is critical quality attribute in applied formulation i.e DPI.
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months. **Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section.**

976.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35149 dated 05.12.2022
	Details of fee submitted	PKR 30,000/- dated 28.10.2022
	The proposed proprietary name / brand name	**SBT Rota capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Salbutamol as Sulphate……200mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	β_2 adrenergic agonist, bronchodilator
	Reference to Finished product specifications	As per innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Ventolin Rotacap 200mcg TGA (Australia) approved
	For generic drugs (me-too status)	Breavent 200mcg capsule Highnoon Laboratories Reg. No. 044593
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for **three years.** New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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, 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, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D,F,C,N,O & unspecified impurity, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(SS-0010613, SS-0010415 and SS-0010516)
	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, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Breavent 200mcg capsule by Highnoon Laboratories Batch No R102 by performing quality tests (Identification, Assay and standard weight against SBT Rota capsule
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.
STABILITY STUDY DATA		
Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra	

	State, India		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Not provided		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-55	T-56	T-57
Batch Size	500 Caps	500 Caps	500 Caps
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	03-01-2022	03-01-2022	03-01-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
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)	Not provided

Remarks of Assessor (DD PEC[XX]):

1) Label claim of RRA approved formulation (Ventolin 200 microgram, powder for inhalation, hard capsule) is as follows:

   Each capsule contains 241 microgram salbutamol sulphate equivalent to 200 microgram salbutamol

   Firm has not provided information regarding potency adjustment (salt form)

2) **3.2.P.5** Applied formulation is available in BP monograph while specifications/ acceptance criteria of quality parameters tested (assay, uniformity of delivered dose, particle size distribution) were not as per BP monograph. Moreover, water content has not been determined as mentioned in BP.
3) **3.2.S.4** Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer

4) **3.2.S.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 / API manufacture.
5) **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
6) **3.2.P.2** In Pharmaceutical equivalence study identification and Assay was mentioned for Budesonide and Formoterol instead of salbutamol. Moreover, batch no of both Test product and Reference product to be provided.
7) **3.2.P.2** Batch formula for proposed commercial batch size should 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.
8) **3.2.P.2** Detailed Analytical method validation studies of Drug product is not provided
9) **3.2.P.2** Detailed Analytical testing method of Drug Product to be provided.
10) **3.2.P.2** Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device /ROTAHALER (name, model, manufacturer, shelf life) provided in pack.
11) **3.2.P.8** Documents for the procurement of API to be submitted.
12) **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.
Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section.

977.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No 69, Block B. Phase I-H, Industrial estate Hattar,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35148 dated 05.12.2022
	Details of fee submitted	PKR 30,000/- dated 28.10.2022
	The proposed proprietary name / brand name	Tybro 18mcg Rota capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Rotacapsule contains: Tiotropium as Bromide Monohydrate……18mcg
	Pharmaceutical form of applied drug	Dry powder for inhalation
	Pharmacotherapeutic Group of (API)	Anticholinergic
	Reference to Finished product specifications	As per innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Spiriva 18mcg inhalation powder MHRA approved
	For generic drugs (me-too status)	Trovair 18mcg capsule

		Highnoon Laboratories Reg. No. 054315
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 12.10.2022 valid for **three years.** New Section Approval granted on 20-09-2021 (Dry Powder inhaler capsule) .
	Name and address of API manufacturer.	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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, 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, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,C,E,F,G&H & related substances specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(MDR-VI/001/11, MDR-VI/002/11and MDR-VI/003/11)
	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, and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Trovair 18mcg capsule by Highnoon pharma, Batch No R102 by performing quality tests (Identification, Assay and standard weight against Tybro 18mcg Rota capsule
	Analytical method validation/verification of product	Summary report of method validation studies submitted including accuracy, precision, linearity, robustness.

STABILITY STUDY DATA	
Manufacturer of API	Vamsi Lab Ltd. A-14/15,MIDC Area,Chincholi, Solapur-413255 Solapur 413255 Maharashtra State, India
API Lot No.	Not provided
Description of Pack	Not provided

(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: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-43	T-44	T-45
Batch Size	500 Caps	500 Caps	500 Caps
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	17-12-2021	17-12-2021	17-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of GMP (No NEW-WHO-GMP/CERT/PD/75003/2018/11/25587 valid till dated 02.11.2021 License retention certificate No 25-PD/29 dated 22/01/2018 valid till 31/12/2022 issued by FDA (Maharashtra state)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
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)	Not provided

Remarks of Assessor (DD PEC[XX]) :

1) Label claim of RRA approved formulation (SPIRIVA 18 microgram, inhalation powder, hard capsule) is as follows:

Each capsule contains 22.5 microgram tiotropium bromide monohydrate equivalent to 18 microgram tiotropium.

The delivered dose (the dose that leaves the mouthpiece of device) is 10 microgram tiotropium.

Firm has not provided information regarding potency adjustment (salt form) and delivered dose.

2) The finished product specifications include acceptable tests and limits for ***appearance, identity (HPLC and ultra violet), assay, content uniformity, water content, degradation products, mean delivered dose, uniformity of delivered dose, aerodynamic particle size, foreign particulate matter, amorphous content and microbial purity.***
https://www.tga.gov.au/sites/default/files/auspar-tiotropium-190613.pdf

while firm has mentioned finished product specifications including weight variation, identification, uniformity of delivered dose, particle size distribution, and Assay only. same have been tested during stability studies as well. Tests like **content uniformity, water content, mean delivered dose, foreign particulate matter, amorphous content and microbial purity** to be performed**.**

3) As per Public assessment report of **Tiogiva 18mcg Inhalation Powder** (MHRA approved) quality parameters such as dissolution testing, particle size distribution and delivered dose testing to be compared while firm has performed tests such as Identification, Assay and standard weight only

https://mhraproducts4853.blob.core.windows.net/docs/448c8da22b062d7f6226d1ed404ff80765b705aa

4) **3.2.S.4** Detailed analytical procedures for the testing of drug substance to be provided by both Drug product and Drug Substance manufacturer
5) **3.2.S.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 / API manufacture.
6) **3.2.S.4** Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided
7) **3.2.P.2** Batch formula for proposed commercial batch size should 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

8) **3.2.P.2** Detailed Analytical method validation studies of Drug product is not provided

9) **3.2.P.2** Description of Packaging (Container closure system) is to be provided, also provide details of metered dose inhalation device /Handihaler (name, model, manufacturer, shelf life) provided in pack.

10) **3.2.P.8** Documents for the procurement of API to be submitted.

11) **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.
Registration Board further advised to submit the registration status of previously registered products for "Sachet (general) section.

New DML:

3) M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan , CLB in its 283rd meeting held on 28th October, 2021, has considered and approved the grant of DML with following three sections:

- **Tablet (General).**
- **Capsule (General).**
- **Oral Dry Powder Suspension (General).**

978.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 612 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 30.11.2022
	The proposed proprietary name / brand name	**LEVOTEL 250mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin as hemihydrate.....250 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOFLOXACIN Tablets 250mg" Approved by Health USFDA manufactured by TEVA
	For generic drugs (me-too status)	LEFLOX TABLETS 250mg (Reg. No.: 026164) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot no. 29 – 30, Sector 27 Korangi Industrial Area, Karachi
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Levofloxacin hemihydrate 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 (A, B & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: DC-004-1512001,DC-004-1512002,DC-004-

		1512003
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tavanic 250 mg tablet by sanofi aventis by performing quality tests (Identification, Assay, Dissolution, disintegration time). CDP has been performed against the same brand that is **Tavanic 250 Tablet** by sanofi aventis (Batch no. B0029) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8) against test product (Batch no. T001). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	5-2022	5-2022	5-2022
Date of Initiation	23-05-2022	23-05-2022	23-05-2022
No. of Batches	03		

Administrative Portion

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

Remarks of Assessor (DD PEC[XX]):

1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
3.2.S.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 / API manufacture.
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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 Batch formula for proposed commercial batch size should 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.
3.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product.
3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

979.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 613 dated 06.01.2023
	Details of fee submitted	PKR 30,000/-: dated 01.12.2022
	The proposed proprietary name / brand name	LEVOTEL 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Levofloxacin as hemihydrate.....500 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOFLOXACIN Tablets 500mg" Approved by Health USFDA manufactured by TEVA
	For generic drugs (me-too status)	LEFLOX TABLETS 500mg (Reg. No.: 026163) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot no. 29 – 30, Sector 27 Korangi Industrial Area, Karachi
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Levofloxacin hemihydrate 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 (A, B & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: DC-004-1512001,DC-004-1512002,DC-004-1512003
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Tavanic 500 mg tablet** by sanofi aventis by performing quality tests (Identification, Assay, Dissolution, Disintegration time).

		CDP has been performed against the same brand that is Tavanic 500 Tablet by sanofi Aventis (Batch No CRD0020) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8) against Test product (Batch No T001). The values for f1 and f2 are in the acceptable range. CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	5-2022	5-2022	5-2022
Date of Initiation	24-05-2022	24-05-2022	24-05-2022
No. of Batches	03		

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

Remarks of Assessor (DD PEC^{XX}):
1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
3.2.S.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 / API manufacture.
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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.P.2 Batch formula for proposed commercial batch size should 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.
3.P.2.1.1 Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product.
3.2.P.2 Submit revised CDP report for Levotel tablet 500mg since CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)
3.2.P.8 Documents for the procurement of API to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

980.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 610 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 01.12.2022
	The proposed proprietary name / brand name	**Sulvipride 25 mg Tablets**
	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)	Antipsychotic
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOPRAID 25 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	For generic drugs (me-too status)	Vesulpid Tablets 25mg by M/s Martin Dow Pharmaceutical(Pakistan) Ltd, Reg. No. 041008

	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	Levosulpiride is not present in any official monograph. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, 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 12 months Batches:LSP0010415,LSP0020515,DC-LSP0030515
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Levopraid 25 mg tablet** (Batch No AQ1801R) by Pacific pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Disintegration time and weight of tablet) against Test product i.e Sulvipride 25mg Tablet (Batch No T001) CDP has been performed against the same brand that is Levopraid 25mg Tablet by Pacific pharmaceuticals in Acid media (pH 1.0-1.2), Acetate medium (Ph 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.		
API Lot No.	LSP0260120		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	6-2022	6-2022	6-2022
Date of Initiation	4-6-2022	4-6-2022	4-6-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/20021839 issued by Food and Drug Control Administration , Gujrat state India **valid till 10.02.2022**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
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)	Not provided

Remarks 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** 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 / API manufacture.
  - **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.S.4** Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
  - **3.2.P.2** CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablets or Sulvipride 50 mg Tablet.
  - **3.2.P.2** Batch formula for proposed commercial batch size should 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
  - **3.2.P.8** Documents for the procurement of API to be submitted.

• **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.		
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.		
981.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 611 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 01.12.2022
	The proposed proprietary name / brand name	**Sulvipride 50 mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levosulpiride.....50mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	For generic drugs (me-too status)	Vesulpid Tablets 50mg by M/s Martin Dow Pharmaceutical(Pakistan) Ltd, Reg. No. 041012
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	Levosulpiride is not present in any official monograph. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, 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 12 months Batches:LSP0010415,LSP0020515,DC-LSP0030515
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Levopraid 50 mg tablet** (Batch No AP0405R) by Pacific pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Disintegration time and weight of tablet) against Test product i.e Sulvipride 50mg Tablet (Batch No T001) CDP has been performed against the same brand that is Levopraid 50mg Tablet by Pacific pharmaceuticals in 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 Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.		
API Lot No.	LSP0260120		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab

Manufacturing Date		6-2022	6-2022	6-2022
Date of Initiation		13-6-2022	13-6-2022	13-6-2022
No. of Batches		03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/20021839 issued by Food and Drug Control Administration , Gujrat state India **valid till 10.02.2022**	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	
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)	Not provided	

Remarks 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** 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 / API manufacture.
  - **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.S.4** Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
  - **3.2.P.2** For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in phosphate buffer medium (pH 4.5) as per CDP report.
  - **3.2.P.2** Batch formula for proposed commercial batch size should 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
  - **3.2.P.8** Documents for the procurement of API to be submitted.
  - **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

982.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 36729 dated 16.12.2022
	Details of fee submitted	PKR 30,000/- dated 26.10.2022
	The proposed proprietary name / brand name	**CIPROTEL 250mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl eq.to Ciprofloxacin.....250 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO® (ciprofloxacin hydrochloride) tablet, 250 mg USFDA Approved .
	For generic drugs (me-too status)	Ciplet 500mg Tablets By M/s Indus Pharma Karachi.(Reg.# 044461)
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ciprofloxacin Hydrochloride is present in USP/BP. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A, B,C,D & E, 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: B#00510011/003/2014, B#00510011/004/2014, B#00510011/005/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Ciproxin 500 mg tablet (Batch No C122) by Bayer Pharma by performing quality tests (Identification, Assay, Dissolution, Average weight) against Test product (Batch No C-T001) CDP has been performed against the same brand that is Ciproxin 500 Tablet by Bayer Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	00510011/178/2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	20-10-2021	20-10-2020	20-10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (drug substance is from local source)

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)	Not provided

Remarks of Assessor (DD PEC[xx]):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.
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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.
3.2.S.4 In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.
3.2.P.2: Potency adjustment of Drug substance as provided in Batch formula, need to be justified. Since quantity of Drug substance mentioned as 593.64 mg for 500mg tablet and 296.82mg for 250mg tablet.
3.P.2.1.1 Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate) is not provided since said excipients are not found in innovator/reference product.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

983.	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 36728 dated 16.12.2022
	Details of fee submitted	PKR 30,000/- dated 26.10.2022
	The proposed proprietary name / brand name	**CIPROTEL 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl eq.to Ciprofloxacin.....500 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product	USP

	specifications	
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO® (ciprofloxacin hydrochloride) tablet, 500 mg USFDA Approved .
	For generic drugs (me-too status)	Ciplet 500mg Tablets By M/s Indus Pharma Karachi.(Reg.# 044462)
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ciprofloxacin Hydrochloride is present in USP/BP. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A, B,C,D & E, 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: B#00510011/003/2014, B#00510011/004/2014, B#00510011/005/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Ciproxin 500 mg tablet (Batch No C122) by Bayer Pharma by performing quality tests (Identification, Assay, Dissolution, Average weight) against Test product (Batch No C-T001) CDP has been performed against the same brand that is Ciproxin 500 Tablet by Bayer Pharma in

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

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.	00510011/178/2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	20-10-2021	20-10-2020	20-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (drug substance is from local source)
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)	Not provided

Remarks of Assessor (DD PEC^{XX}):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.

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.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.S.4 In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.

3.2.P.2: Potency adjustment of Drug substance as provided in Batch formula, need to be justified. Since quantity of Drug substance mentioned as 593.64 mg for 500mg tablet and 296.82mg for 250mg

tablet. **3.P.2.1.1**Compatibility of the Drug Substance(s) with excipient (Sodium starch glycolate) is not provided since said excipients are not found in innovator/reference product. **3.2.P.8** Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

New DML:

4) M/s Himark Laboratories Private Limited Plot 37-A, Sundar Industrial Estate Lahore , CLB in its 271st meeting held on 12th September 2019, has considered and approved the grant of DML with following three sections:
   - **Tablet (General & General Antibiotic) section.**
   - **Capsule (General & General Antibiotic) section.**
   - **Dry Powder Suspension (General & General Antibiotic) section.**
   - **Oral Liquid Syrup section.**
   - **Sachet (General).**
   - **Cream/ointment (General) section.**

984.	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. 39628 dated 30.12.2022
	Details of fee submitted	PKR 30,000/- dated 12/01/2022
	The proposed proprietary name / brand name	Hidom 10 mg film coated tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** Domperidone (as Maleate): 10 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidopaminergic agent
	Reference to Finished product specifications	BP
	Proposed Pack size	5 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Motilium 10mg Tablet by M/s Janssen Pharmaceutical, MHRA Approved.
	For generic drugs (me-too status)	Domel Tablet by M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Reg. No. 028759
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Tablet (General & General Antibiotic) section was approved.

	Name and address of API manufacturer.	Sainor Life Sciences (Pvt) Ltd., Address: Admin Office: Flat No 110 First Floor West Wing SVSS Nivas Czech Colony Sanath Nagar, Hyderabad 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 Domperidone maleate is available in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances (impurity A, B, C, D, E,F & unspecified and total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batch No DM 190222014 DM 190232014 DM 190242014
	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	The Firm has performed pharmaceutical equivalence & CDP of their developed formulation Hidom 10 mg Tablet with comparator product Motilium 10 mg Tablet by M/s Aspin Pharma. Quality parameters such as Identification, DT, Dissolution, uniformity of dosage unit and Assay CDP has been performed against the same brand that is Motilium 10 mg Tablet by M/s Aspin Pharma 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	Sainor Life Sciences (Pvt) Ltd., Address: Admin Office: Flat No 110 First Floor West Wing SVSS Nivas Czech Colony Sanath Nagar, Hyderabad India		
API Lot No.	Not provided		
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-50DM	T-51DM	T-52DM
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	20-06-2021	20-06-2021	20-06-2021
No. of Batches	03		

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

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Copy of GMP certificate No. E-1632848/DD/DCA/VSP/2022 issued by Drug Control Administration Visakhapatnam India valid till 27/05/2023.	Complied
2.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	IR spectrum of Domperidone is provided	Complied

3.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies performed by the Drug substance manufacturer is provided.	Firm provided Analytical Method Verification studies of Drug substance as performed by Drug product manufacturer
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 / API manufacture	CoA of Batch No DM19044 has been provided from both Drug Substance and Drug product manufacturer.	Complied
5.	Analytical method of Drug Substance (assay, column dimensions) are not as per BP. Clarify it.	Analytical method of Drug Substance provided as per BP	Complied
6.	COA of primary / secondary reference standard including source and lot number to be provided	CoA of working standard Domperidone maleate has been provided as under Batch No: WS/DM-61160200 Manufacturer: Sainor Life Sciences (Pvt) Ltd.,	Complied
7.	Batch no of innovator product and test product has not been mentioned under CDP.	Batch no of innovator product B 437 Batch no of Test product T-01	Complied
8.	Batch formula for proposed commercial batch size should 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	Provided	Complied
9.	Potency adjustment (salt factor) of Drug substance to be provided in Batch formula.	Provided	Complied
10.	Compatibility of the Drug Substance(s) with excipients (Talcum and Primojel) is not provided.	Provided There was neither loss of assay nor any degradant was detected.	Complied
11.	Documents for the procurement of API (approval from DRAP) to be submitted.	Copy of Invoice No DM/02232/21 DATE 29.04.2021 submitted confirming import of Domperidone 0.050 Kg Batch No DM19044. Approval from DRAP (I&E) Lahore dated 26.12.2019 has been provided.	Complied

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.**

985.	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. 604 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 12/01/2022
	The proposed proprietary name / brand name	Hidom 5 mg / 5 ml Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml suspension contains: Domperidone……5 mg
	Pharmaceutical form of applied drug	Yellow color sweet homogeeous suspension filled in 60 ml amber glass bottle
	Pharmacotherapeutic Group of (API)	Anti-dopaminergic agent
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	60 ml, 90 ml, 120 ml, 400 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Domperidone 1mg/ml Suspension by M/s Wockhardt UK Ltd, MHRA Approved.
	For generic drugs (me-too status)	Motilium Suspension 5 mg /5 ml by M/s Aspin Pharma, Reg. No. 006527
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Oral Liquid Syrup section was approved.
	Name and address of API manufacturer.	Sainor Life Sciences (Pvt) Ltd., Address: Admin Office: Flat No 110 First Floor West Wing SVSS Nivas Czech Colony Sanath Nagar, Hyderabad 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 Domperidone is available in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances (impurity A, B, C, D, E,F & unspecified and total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batch No DM 190442012 DM 190452012 DM 190462012
	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	The Firm has performed pharmaceutical equivalence of their developed formulation Hidom Suspension with comparator product Motilium Susp. 5 mg/5ml Susp. By M/s Aspin Pharma. Quality parameters such as Identification, Assay and deliverable volume were compared.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Sainor Life Sciences (Pvt) Ltd., Address: Admin Office: Flat No 110 First Floor West Wing SVSS Nivas Czech Colony Sanath Nagar, Hyderabad India		
API Lot No.	DM19044		
Description of Pack (Container closure system)	Amber glass bottle in 60ml pack sealed with aluminium cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	13-05-2021	13-05-2021	13-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/67649/2018/11/25185 issued by Food and Drug Administration India valid till 04/10/2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No DM/02232/21 DATE 29.04.2021 submitted confirming import of Domperidone 0.050 Kg Batch No DM19044
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 is maintained manually.
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):

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Copy of GMP certificate No. E-1632848/DD/DCA/VSP/2022 issued by Drug Control Administration Visakhapatnam India valid till 27/05/2023.	Complied
2.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	IR spectrum of Domperidone is provided	Complied
3.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Analytical Method Verification studies performed by the Drug substance manufacturer is provided.	Firm provided Analytical Method Verification studies of Drug substance as performed by Drug product manufacturer
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 / API manufacture	CoA of Batch No DM19044 has been provided from both Drug Substance and Drug product manufacturer.	Complied
5.	Batch no of innovator product and test product has not been mentioned under CDP.	Batch no of innovator product A0614 Batch no of Test product T-01	Complied
6.	Batch formula for proposed commercial batch size should be provided that includes a	Provided	Complied

	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		
7.	Quantity of Drug substance as provided in Batch formula (5.395 mg) to be justified.	It was a typing mistake; actual quantity was 5mg/5ml instead of 5.395mg. No overage was added in formulation.	Complied
8.	Compatibility of the Drug Substance(s) with excipients (Xanthan gum, sodium citrate and citric acid anhydrous) is not provided.	There was neither loss of assay nor any degradant was detected.	Complied
9.	Documents for the procurement of API (approval from DRAP) to be submitted.	Copy of Invoice No DM/02232/21 DATE 29.04.2021 submitted confirming import of Domperidone 0.050 Kg Batch No DM19044. Approval from DRAP (I&E) Lahore dated 26.12.2019 has been provided.	Complied

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.**

New DML:

5) M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66 Mouza Mirpur Kehna, Tehsil Sharkpur, District Sheikhupura , CLB in its 285th meeting held on 17th & 18th March 2022, has considered and approved the grant of DML with following three sections:

- **Tablet (General).**
- **Capsule (General).**
- **Oral Dry Powder Suspension (General).**
- **Sachet (General).**

986.	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. 37337 dated 21/12/2022
	Details of fee submitted	PKR 30,000/-: dated 19/12/2022

	The proposed proprietary name / brand name	CPX-250mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains:- Ciprofloxacin HCl Eq. to Ciprofloxacin …… …….250mg USP Specification
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's, 10x10's, Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin film coated tablets (MHRA Approved)
	For generic drugs (me-too status)	Cip Val 250mg Tablet M/s GlaxoSmithKline Pakistan Limited , Reg. No. 050687
	GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022. Tablet General section was approved on 29.04.2022
	Name and address of API manufacturer.	M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ciprofloxacin Hydrochloride is present in USP/BP. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug 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: B#00510011/003/2014, B#00510011/004/2014, B#00510011/005/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Cip Val 250mg tablet Batch No 3G4A by GSK Pharma. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and DT) against Test product CPX-250mg Tablet Batch No TT001. CDP has been performed against the same brand that is CPX-250mg Tablet by ICU Pharma 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan		
API Lot No.	00510011/015/2022		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TT-001	TT-002	TT-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	18-05-2022	18-05-2022	18-05-2022
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 GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (drug substance is from local source)
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	Submitted

	stability chambers (real time and accelerated)	

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Firm has again submitted Copy of GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.	Not complied
2.	In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.	Firm has submitted CoA of Drug Substance wherein result for test "Residue on Ignition" has been mentioned.i.e 0.06%	Complied
3.	Compatibility of the Drug Substance(s) with excipient Lactose, cross carmellose sodium, Sodium Lauryl Sulphate, Primojel and Talcum is not provided since said excipients are not found in innovator/reference product.	Compatibility of the Drug Substance(s) with aforementioned excipients has been performed. (Binary mixtures). There was no loss of assay observed with selected excipients.	Complied
4.	CoA, Raw data sheet and chromatograms are provided for 0 and 3 months only (of all three stability batches), same to be provided for 6th month as well.	Provided	Complied

Decision: Approved.

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

Registration letter will be issued upon submission of Pharmaceutical equivalence & CDP studies against innovator product i.e., Ciproxin of M/s Bayer Pakistan Pvt Ltd.

987.	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. 37336 dated 21/12/2022

	Details of fee submitted	PKR 30,000/-: dated 19/12/2022
	The proposed proprietary name / brand name	**CPX-500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains:- Ciprofloxacin HCl Eq. to Ciprofloxacin …… …….500mg USP Specification
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's, 2x10's, 10x10's, Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin film coated tablets (MHRA Approved)
	For generic drugs (me-too status)	Cip Val 500mg Tablet M/s GlaxoSmithKline Pakistan Limited , Reg. No. 050688
	GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022.
	Name and address of API manufacturer.	M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Ciprofloxacin Hydrochloride is present in USP/BP. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug 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: B#00510011/003/2014, B#00510011/004/2014, B#00510011/005/2014
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Cip Val 500mg tablet (Batch No YU5P) by GSK Pharma. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and DT) against Test product i.e CPX-500mg Tablet (Batch No TT004). CDP has been performed against the same brand that is CPX-500mg Tablet by ICU Pharma 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 Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan		
API Lot No.	00510011/015/2022		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TT-004	TT-005	TT-006
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	18-05-2022	18-05-2022	18-05-2022
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 GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (drug substance is from local source)
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	Submitted

	stability chambers (real time and accelerated)	

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Firm has again submitted Copy of GMP certificate No. 129/2020 dated 02.09.2020 based on inspection dated 22.06.2020 valid till Two Years issued by DRAP.	Not complied
2.	In USP monograph specification of Drug Substance included test "Residue on Ignition" (NMT 0.1%) while same has not been performed by firm.	Firm has submitted CoA of Drug Substance wherein result for test "Residue on Ignition" has been mentioned.i.e 0.06%	Complied
3.	Compatibility of the Drug Substance(s) with excipient Lactose, cross carmellose sodium, Sodium Lauryl Sulphate, Primojel and Talcum is not provided since said excipients are not found in innovator/reference product.	Compatibility of the Drug Substance(s) with aforementioned excipients has been performed. (Binary mixtures). There was no loss of assay observed with selected excipients.	Complied
4.	CoA, Raw data sheet and chromatograms are provided for 0 and 3 months only (of all three stability batches), same to be provided for 6th month as well.	Provided	Complied

Decision: Approved.

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

Registration letter will be issued upon submission of Pharmaceutical equivalence & CDP studies against innovator product i.e., Ciproxin of M/s Bayer Pakistan Pvt Ltd.

988.	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. 35676 dated 08/12/2022
	Details of fee submitted	PKR 30,000/-: dated 06/12/2022
	The proposed proprietary name / brand name	**Eso-Rose 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	1x10's, 2x7's, 100's, Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Nexium capsule
	For generic drugs (me-too status)	Nexum capsule 20mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 033890
	GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022. Capsule General section was approved on 29.04.2022
	Name and address of API (pellets) manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: B#EMZ044858, B#EMZ044632, B B#EMZ045058

	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 brand leader that is **Nexum Capsule 20mg** Batch No C01004 by GSK Pharma. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation) against Test product **Eso-Rose 20mg Capsule** Batch No CT004. CDP has been performed against the same brand that **Nexum Capsule 20mg** 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad		
API/Pellets Lot No.	EMZ046515		
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: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CT-004	CT-005	CT-006
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	08-2022	08-2022	08-2022
Date of Initiation	11-08-2022	11-08-2022	11-08-2022
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-22) dated 25.03.2022 based on inspection dated 11.02.2019 valid till 10.02.2022 issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (pellets are from local source)

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 Assessor (DD PEC [xx]):

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Firm has again submitted Copy of GMP certificate No. F.3-26/2019 Addl.Dir (QA&LT-22) dated 25.03.2022 based on inspection dated 11.02.2019 valid till 10.02.2022 issued by DRAP.	Not complied
2.	COA of primary / secondary reference standard including source and lot number to be provided. Since already provided CoA is of omeprazole (working standard) instead of Esomeprazole.	*According to USP we used omeprazole as working standard for analysis of Esomeprazole DR capsule.*	Justified
3.	Compatibility of the Drug Substance(s) with excipient Microcrystalline cellulose, Titanium dioxide and Diethyl phthalate (Eso-Rose 20mg Capsule) is not provided since said excipients are not found in innovator/reference product	*Our product contains Esomeprazole DR pellets which are ready to fill and does not require any preparation and are filled into empty hard gelatin shells received from the supplier.*	Same may be asked from pellet manufacturer by finished product manufacturer.
4.	Summary data sheets, CoA, Raw data sheet and chromatograms are to be provided for 6th month as well.	Provided	6th month stability data was already submitted dated 15.02.2023 (Dy No. 4371 DRAP (R&I)). Same has been evaluated.

Decision: Approved.

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

Registration Board further decided to send reference to Licensing Division about excipients used by M/s Vision pharmaceuticals for formulating Esomeprazole magnesium trihydrate pellets, since excipients such as Microcrystalline cellulose, Titanium dioxide and Diethyl phthalate are not found in innovator/reference product, hence compatibility study of the Drug Substance(s) with said excipients is required.

989.	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. 35677 dated 08/12/2022
	Details of fee submitted	PKR 30,000/-: dated 06/12/2022
	The proposed proprietary name / brand name	**Eso-Rose 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	1x10's, 2x7's, 100's, Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved Nexium capsule
	For generic drugs (me-too status)	Nexum capsule 40mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 033891
	GMP status of the Finished product manufacturer	New DML granted dated 28-04-2022. Capsule General section was approved on 29.04.2022
	Name and address of API (pellets) manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: B#EMZ044440, B#EMZ044265, B#EMZ044152.
	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 brand leader that is **Nexum Capsule 40mg** Batch No C02013 by GSK Pharma. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation) against Test product **Eso-Rose 40mg Capsule** Batch No CT001. CDP has been performed against the same brand that **Nexum Capsule 40mg** 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad		
API/Pellets Lot No.	EMZ046487		
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: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CT-001	CT-002	CT-003
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	06-07-2022	06-07-2022	06-07-2022
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-22) dated 25.03.2022 based on inspection dated 11.02.2019 valid till 10.02.2022 issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (pellets are from local source)
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 Assessor (DD PEC [xx]):

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Firm has again submitted Copy of GMP certificate No. F.3-26/2019 Addl.Dir (QA&LT-22) dated 25.03.2022 based on inspection dated 11.02.2019 valid till 10.02.2022 issued by DRAP.	Not complied
2.	COA of primary / secondary reference standard including source and lot number to be provided. Since already provided CoA is of omeprazole (working standard) instead of Esomeprazole.	*According to USP we used omeprazole as working standard for analysis of Esomeprazole DR capsule.*	Justified
3.	Compatibility of the Drug Substance(s) with excipient Microcrystalline cellulose, Titanium dioxide and Diethyl phthalate (Eso-Rose 20mg Capsule) is not provided since said excipients are not found in innovator/reference product	*Our product contains Esomeprazole DR pellets which are ready to fill and does not require any preparation and are filled into empty hard gelatin shells received from the supplier.*	Same may be asked from pellet manufacturer by finished product manufacturer.
4.	Summary data sheets, CoA, Raw data sheet and chromatograms are to be provided for 6th month as well.	Provided	6th month stability data was already submitted dated 15.02.2023 (Dy No. 4372 DRAP (R&I)). Same has been evaluated.

Decision: Approved.

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

commitment submitted in the registration application **Registration Board further decided to send reference to Licensing Division about excipients used by M/s Vision pharmaceuticals for formulating Esomeprazole magnesium trihydrate pellets, since excipients such as Microcrystalline cellulose, Titanium dioxide and Diethyl phthalate are not found in innovator/reference product, hence compatibility study of the Drug Substance(s) with said excipients is required.**

B) Priority consideration on account of Export Facilitation:

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements

Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 29th December 2022.

990.	Name, address of Applicant / Marketing Authorization Holder	M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plots No. 26-27 & 63-67, sector-27 Korangi Industrial Area, Karachi – 74900, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3450 dated 29/11/2022
	Details of fee submitted	PKR 30,000/- dated 2/10/2022
	The proposed proprietary name / brand name	**Raceca 10mg Granules for Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: - Racecadotril ……10mg
	Pharmaceutical form of applied drug	Granules for oral suspension
	Pharmacotherapeutic Group of (API)	Enkephalinase Inhibitor
	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	Hidrasec 10 mg, Granules for oral suspension by SOPHARTEX 21 rue de Pressoir 28500 Vernouillet France, MHRA.
	For generic drugs (me-too status)	Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited. Reg. No. 087082
	GMP status of the Finished product manufacturer	GMP inspection conducted on 24/12/2021 Valid till: 17/12/2023. Sachet section (General) regularized on 21.07.2020

	Name and address of API manufacturer.	Shandong Qidu Pharmaceutical Co., Ltd. No.17, Hongda Road, Linzi District, Zibo City, Shandong, province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities (A,C,E&F) and unspecified impurities, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Not provided
	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 not performed CDP has been performed against the same brand that is Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited (Batch No SXN734) in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including System Suitability, Precision, Specificity, linearity, range, accuracy, and repeatability.

STABILITY STUDY DATA

Manufacturer of API	Shandong Qidu Pharmaceutical Co., Ltd.		
API Lot No.	200402		
Description of Pack (Container closure system)	Inner packaging and Intermediate packaging: Laminated film (PET/AI/PE) for pharmaceutical packaging; Outer packing: Cardboard drums		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			TR-4/ RCT 10mg

	TR-2/ RCT 10mg	TR-3/ RCT 10mg	
Batch Size	2000 Sachet	2000 Sachet	2000 Sachet
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Canazin tablet 300mg Minutes of 289th Meeting of Registration Board (14-16 May,2019)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No. Lu 2160064 issued by Shandong Medical Products Administration valid till 23/11/2025. GMP certificate No SD20180700 VALID TILL 22.05.2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of Invoice No.22200730 dated 25/05/2021 is submitted wherein the permission to import Racecadotril **150gm Batch No 200402** for the purpose of test/analysis and stability studies is granted. • DRAP AD attestation Date is 28-9-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
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):

Sr.#	Observation	Reply	Remarks
1.	COA of primary / secondary reference standard including source and lot number to be provided	Provided	complied
2.	Stability studies of Drug Substance to be provided.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months. **190101, 190301 and 190401**	Complied
3.	Pharmaceutical equivalence to be provided against	Pharmaceutical equivalence study has been	Complied

	innovator/comparator product by performing quality tests.	performed against the same brand that is Hidrasec 10mg Granules for Oral Suspension by Abbott Laboratories (Pakistan) Limited (Batch No SXN734)	
4.	Summary data sheets, CoA, Raw data sheet and chromatograms are to be provided for three batches against each time point (both real time and accelerated studies)	Summary data sheets, CoA, Raw data sheet and chromatograms are provided for all three batches **TR2/RCT**, **TR3/RCT** and **TR4/RCT** against each time point.	Complied

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**

Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 12th January 2023.

991.	Name and address of manufacturer / Applicant	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industria Area, Islamabad.**
	Brand Name +Dosage Form + Strength	Obetab Tablets 5mg
	Composition	Each Film Coated Tablet Contains: Obeticholic Acid…….……5mg
	Diary No. Date of R& I & fee	Dy. No. 16633 dated 07-03-2019, Fee Rs: 50,000/- dated 07-03-2019 Stability data submission on 22.02.2022 Dy No 4963
	Pharmacological Group	Bile Acid Analog and Farnesoid X Receptor Agonist
	Type of Form	Form: 5D
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	Ocaliva Tablets (USFDA Approved)
	Me-too status	Not provided
	GMP status	GMP inspection report dated 09.11.2018 is provided

STABILITY STUDY DATA	
Manufacturer of API	M/s Virupaksha Organics Limited**.** Survey. No. 10, Gaddapotharam Village, Jinnaram Mandal, Sangareddy Dist. 502319, Telangana, India.
API Lot No.	AOBTC0118001
Description of Pack (Container closure system)	Alu-Alu blister packed in uni carton
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Real Time: 0, 3, 6 months Accelerated: 0, 3, 6 months		
Batch No.	01	02	03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	12-12-2018	14-12-2018	17-12-2018
No. of Batches	03		
Date of Submission	22-02-2022		

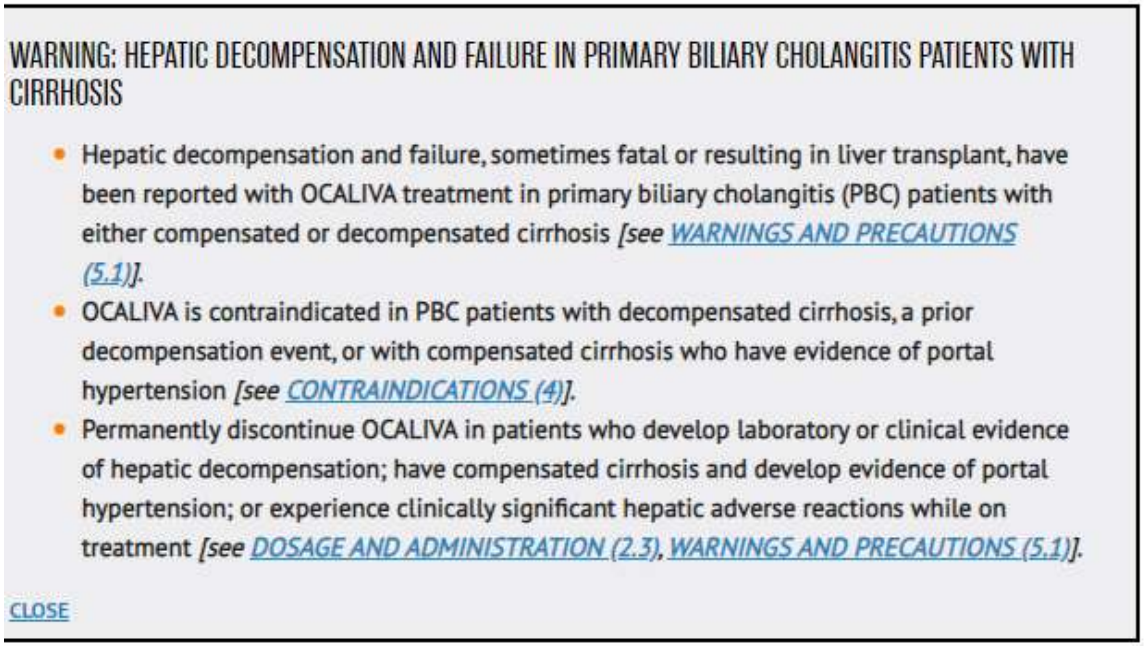
DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
15.	Reference of previous approval of applications with stability study data of the firm	The firm has submitted Reference of previous approva of applications with stability study data as Xetine 10mg tablet approved in 294th meeting of Registration Board.
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Obeticholic Acid** (Batch# AOBTC0118001) **API Manufacturer:** Copy of COA from M/ Virupaksha Organics Limited India was submitted. **Finished Product Manufacturer:** COA from Werrick Pharmaceuticals, Islamabad, was submitted.
17.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from Finished Produc Manufacturer is provided only
18.	Stability study data of API from API manufacturer	Not provided
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of updated GMP Certificate No L.Dis.No:70109/TS/2021, Dated 27-10-2021, valid up to 26-10-2022. in the name of M/s Virupaksha Organic Limited India.
20.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. VPPL/EXP/127/17-18 Dated 20-03-2018, attested by AD (I&E) DRAP on 03.04.2018 confirming import of API (0.12 Kg) Batch No AOBTC0118001
21.	Protocols followed for conduction of stability study.	Submitted
22.	Method used for analysis of FPP	Submitted
23.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required.
24.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches:
25.	Record of comparative dissolution data (where applicable)	The Reference Product Ocaliva Tablets 5mg (Obeticholi acid) is not available in Pakistan hence comparative dissolution is not performed.
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

Batch No.	Batch Size	Mfg. Date
01	1500 tablets	12-2018
02	1500 tablets	12-2018
03	1500 tablets	12-2018

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

Remarks of Assessor (DD PEC-XX)
Approved in USFDA with Box warning



WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis *[see WARNINGS AND PRECAUTIONS (5.1)]*.
- OCALIVA is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension *[see CONTRAINDICATIONS (4)]*.
- Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension; or experience clinically significant hepatic adverse reactions while on treatment *[see DOSAGE AND ADMINISTRATION (2.3), WARNINGS AND PRECAUTIONS (5.1)]*.

CLOSE

Sr.#	Observation	Reply	Remarks
1.	Provide updated GMP status of both Drug substance and Drug product manufacturer.	Updated GMP from Drug substance manufacturer Certificate No.L.Dis.No:100509/TS/2022, Dated 21-12-2022, valid up to 20-12-2023. in the name of M/s Virupaksha Organics Limited India. GMP certificate of Drug Product manufacturer based on inspection dated 12.08.2022 valid till 2 years, submitted	Complied
2.	Provide Method used for analysis of API from API Manufacturer	Provided	Complied
3.	Physicochemical characteristics of the active substance that impact the quality of the finished product are particle size distribution which plays a critical role in the content uniformity and dissolution of the tablets. https://www.ema.europa.eu/en/documents/assessment-report/ocaliva-epar-public-assessment-report_en.pdf However, particle size distribution of active substance has not been controlled /performed either by Drug substance or Dug product manufacturer.	Particle size distribution of active substance has been controlled by Drug Substance manufacturer (performed by X-Ray diffraction) as mentioned in CoA.	Complied
4.	Tests like Sulphated ash particle size distribution and microbial limit have not been performed on Drug substance	Tests like Sulphated ash (residue on ignition) and particle size distribution have been performed by Drug Substance manufacturer as mentioned in CoA however firm commit that microbial	

		limit test will be performed before manufacturing of our product	
5.	Stability study data of API from API manufacturer to be provided.	Stability data of drug substance has been performed for 3 batches i.e AOBTC0217001, AOBTC0217002 and AOBTC0217003 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.	Complied
6.	The finished product release specifications include appropriate tests for this kind of dosage form: appearance, identification (HPLC, TLC), assay (HPLC), degradation products (HPLC), total specified and unspecified impurities (HPLC), dissolution (Ph. Eur.), uniformity of dosage units (Ph. Eur.), water content (Ph. Eur.), microbial limits (Ph. Eur.) https://www.ema.europa.eu/en/documents/assessment-report/ocaliva-epar-public-assessment-report_en.pdf However, tests like water content (Ph. Eur.), microbial limits (Ph. Eur.) have not been performed.	Firm commit that microbial limit test and water content will be performed before launching of product	
7.	Perform CDP against innovator/comparator product and submit report accordingly.	CDP was not performed due to non availability of reference product (ocliva tablet) in Pakistan. Firm commit that they will perform CDP before launching the product.	Generic versions are available in Pakistan.

Decision: Deferred for following reasons:

a) Microbial limit test has not been performed on Drug substance as per innovator product.

b) Tests like water content (Ph. Eur.), microbial limits (Ph. Eur.) have not been performed as per innovator product

c) **CDP has not been performed against innovator/reference/comparator product**.

992.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area Islamabad.
	Brand Name +Dosage Form + Strength	**Obetab Tablets 10mg**
	Composition	Each Film Coated Tablet Contains: Obeticholic Acid……10mg
	Diary No. Date of R& I & fee	Dy. No. 16635 dated 07-03-2019, Fee Rs: 50,000/- dated 07-03-2019.
	Pharmacological Group	Bile Acid Analog and Farnesoid X Receptor Agonist
	Type of Form	Form: 5D
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	Not provided
	Approval status of product in Reference Regulator Authorities	Ocaliva Tablets (USFDA Approved)
	Me-too status	Not provided

	GMP status	GMP inspection report dated 09.11.2018 is provided

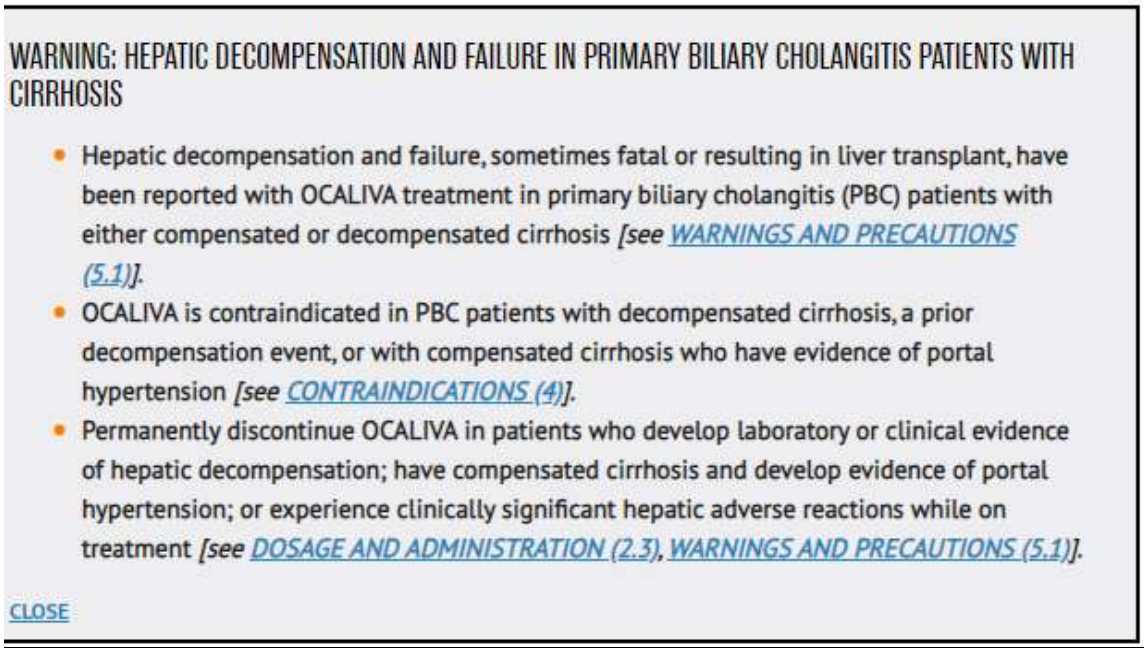
STABILITY STUDY DATA			
Manufacturer of API	M/s Virupaksha Organics Limited**.** Survey. No. 10, Gaddapotharam Village, Jinnaram Mandal, Sangareddy Dist.-502319 Telangana, India.		
API Lot No.	AOBTC0118001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real Time: 0,3, 6 months Accelerated: : 0,3, 6 months		
Batch No.	01	02	03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	14-12-2018	17-12-2018	19-12-2018
No. of Batches	03		
Date of Submission	22-02-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	**Documents to Be Provided**	**Status**
29.	Reference of previous approval of applications with stability study data of the firm	The firm has submitted Reference of previous approval o applications with stability study data.
30.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Obeticholic Acid** (Batch# AOBTC0118001) **API Manufacturer:** Copy of COA from M/s Virupaksh Organics Limited India was submitted. **Finished Product Manufacturer:** COA from Werrick Pharmaceuticals, Islamabad, was submitted.
31.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from Finished Produc Manufacturer is provided only
32.	Stability study data of API from API manufacturer	Not provided
33.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of updated GMP Certificate No L.Dis.No:70109/TS/2021, Dated 27-10-2021, valid up to 26-10 2022. in the name of M/s Virupaksha Organics Limited India.
34.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. VPPL/EXP/127/17-18 Dated 20-03-2018, attested by AD (I&E) DRAP on 03.04.2018 confirming import of API (0.12 Kg) Batch No AOBTC0118001
35.	Protocols followed for conduction of stability study.	Submitted
36.	Method used for analysis of FPP	Submitted
37.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required.

38.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** 01 / 1500 tablets / 12-2018 02 / 1500 tablets / 12-2018 03 / 1500 tablets / 12-2018
39.	Record of comparative dissolution data (where applicable)	The Reference Product Ocaliva Tablets 10mg (Obeticholic acid is not available in Pakistan hence comparative dissolution is not performed.
40.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC-XX)
Approved in USFDA with Box warning



WARNING: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS

- Hepatic decompensation and failure, sometimes fatal or resulting in liver transplant, have been reported with OCALIVA treatment in primary biliary cholangitis (PBC) patients with either compensated or decompensated cirrhosis *[see WARNINGS AND PRECAUTIONS (5.1)]*.
- OCALIVA is contraindicated in PBC patients with decompensated cirrhosis, a prior decompensation event, or with compensated cirrhosis who have evidence of portal hypertension *[see CONTRAINDICATIONS (4)]*.
- Permanently discontinue OCALIVA in patients who develop laboratory or clinical evidence of hepatic decompensation; have compensated cirrhosis and develop evidence of portal hypertension; or experience clinically significant hepatic adverse reactions while on treatment *[see DOSAGE AND ADMINISTRATION (2.3), WARNINGS AND PRECAUTIONS (5.1)]*.

CLOSE

Sr.#	Observation	Reply	Remarks
1.	Provide updated GMP status of both Drug substance and Drug product manufacturer.	Updated GMP from Drug substance manufacturer Certificate No.L.Dis.No:100509/TS/2022, Dated 21-12-2022, valid up to 20-12-2023. in the name of M/s Virupaksha Organics Limited India. GMP certificate of Drug Product manufacturer based on inspection dated 12.08.2022 valid till 2 years, submitted	Complied

2.	Provide Method used for analysis of API from API Manufacturer	Provided	Complied
3.	Physicochemical characteristics of the active substance that impact the quality of the finished product are particle size distribution which plays a critical role in the content uniformity and dissolution of the tablets. https://www.ema.europa.eu/en/documents/assessment-report/ocaliva-epar-public-assessment-report_en.pdf However, particle size distribution of active substance has not been controlled /performed either by Drug substance or Dug product manufacturer.	Particle size distribution of active substance has been controlled by Drug Substance manufacturer (performed by X-Ray diffraction) as mentioned in CoA.	Complied
4.	Tests like Sulphated ash particle size distribution and microbial limit have not been performed on Drug substance	Tests like Sulphated ash (residue on ignition) and particle size distribution have been performed by Drug Substance manufacturer as mentioned in CoA however firm commit that microbial limit test will be performed before manufacturing of our product	
5.	Stability study data of API from API manufacturer to be provided.	Stability data of drug substance has been performed for 3 batches i.e AOBTC0217001, AOBTC0217002 and AOBTC0217003 The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 48 months.	Complied
6.	The finished product release specifications include appropriate tests for this kind of dosage form: appearance, identification (HPLC, TLC), assay (HPLC), degradation products (HPLC), total specified and unspecified impurities (HPLC), dissolution (Ph. Eur.), uniformity of dosage units (Ph. Eur.), water content (Ph. Eur.), microbial limits (Ph. Eur.) https://www.ema.europa.eu/en/documents/assessment-report/ocaliva-epar-public-assessment-report_en.pdf However, tests like water content (Ph. Eur.), microbial limits (Ph. Eur.) have not been performed.	Firm commit that microbial limit test and water content will be performed before launching of product	
7.	Perform CDP against innovator/comparator product and submit report accordingly.	CDP was not performed due to non availability of reference product (ocliva tablet) in Pakistan. Firm commit that they will perform CDP before launching the product.	Generic versions are available in Pakistan.

Decision: Deferred for following reasons:

a) Microbial limit test has not been performed on Drug substance as per innovator product.

b) Tests like water content (Ph. Eur.), microbial limits (Ph. Eur.) have not been performed as per innovator product

c) CDP has not been performed against innovator/reference/comparator product.

Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 29th December 2022.

993.	Name, address of Applicant / Marketing Authorization Holder	SURGE LABORATORIES (PVT.) LTD. Head Office: 5th Floor, Commerce Centre, Hasrat Mohani Road, Karachi.
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals PVT, LTD. 581-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. 24970 dated 02 / 09 / 2022
	Details of fee submitted	PKR 75,000/-: dated 16/06/2022
	The proposed proprietary name / brand name	**Torpicillin IV 2.25g Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin Sodium eq. to Piperacillin….2.0g Tazobactam Sodium eq. to Tazobactam…0.25g
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Carbapenems Wrongly mentioned. Applied drug is penicillin rather than Carbapenem
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	1 glass vial of Powder for Injection + 1 ampoule of 10ml Sterile Water for Injection in a single pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Product TANZO 2.25g Injection (Piperacillin + Tazobactam) (039593) is registered and being marketed by M/s. Bosch Pharmaceuticals Pvt. Ltd (Pakistan)
	GMP status of the Finished product manufacturer	GMP Certificate granted based on inspection dated 02/10/2020 valid for 2 years.
	Name and address of API manufacturer.	**M/s Qilu Tianhe Pharmaceuticals Co. Ltd** 849, Dongjia Town, Licheng District, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Piperacillin + Tazobactam 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 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 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (HF7001D1, HF7002D2, HF7003D3)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tanzo Sterile Dry Powder Injection 2.25g (Piperacillin + Tazobactam) is registered and being marketed by M/s Bosch Pakistan Limited, by performing quality tests (Description, Identification, pH, water content, Reconstitution time, Endotoxin test, Sterility test and 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 Qilu Tianhe Pharmaceuticals Co. Ltd** 849, Dongjia Town, Licheng District, Jinan, Shandong, China		
API Lot No.	KA100715006, KA1007150022		
Description of Pack (Container closure system)	1 glass vial of Powder for Injection + 1 ampoule of 10ml Sterile Water for Injection in a single pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	N5001	N5002	N5003
Batch Size	4250 vials	4160 vials	6380 vials
Manufacturing Date	03-2015	13-2015	04-2015
Date of Initiation	25-05-2015	26-05-2015	12-06-2015
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No 2018001issued by Centre for Evaluation & Certificate of Shandong Food & Drug Administration valid till 24/07/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice no. SL-150202-Z dated 04-02-2015 duly attested by Assistant Director, DRAP, Lahore on 09-02-2015were provided. Total quantity 100Kg.
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 Assessor (DD PEC-XX):

Sr.#	Observation	Observation	Remarks
1.	Contract manufacturing agreement provided dated 01.04.2022 between M/s Stallion Pharmaceuticals Pvt, Ltd and M/s Nabiqasim Industries Pvt, Ltd instead of M/s Surge Laboratories (Pvt.) Ltd.	Contract manufacturing agreement between M/s Stallion Pharmaceuticals Pvt, Ltd and M/s Surge Laboratories (Pvt.) Ltd has been provided dated 31.12.2021.	Complied
2.	Submit valid GMP certificate/inspection report of contact manufacturer i.e M/s Stallion Pharmaceuticals Pvt, Ltd 581-Sundar Industrial Estate, Lahore.	GMP certificate based on inspection dated 20.09.2022, provided valid for 2 years.	Complied
3.	Submit approval letter for relevant section i.e Penicillin dry powder injection from CLB granted to manufacturer.	Section approval letter dated 06.02.2014 submitted wherein Dry Powder Injection (Penicillin) was approved by CLB.	Complied
4.	Mention correct pharmacotherapeutic group and ATC code	Pharmacotherapeutic group was corrected as Antibacterials for systemic use (Penicillin and Beta lactamase inhibitor)	Complied
5.	Title of Drug substance manufacturer mentioned on GMP certificate as **M/s Qilu Tianhe Pharmaceuticals Co. Ltd** while tile of drug substance manufacturer mentioned on rest of documents as **Shandong Anxin Pharmaceutical Co**	Company name/title has been changed from **M/s Qilu Tianhe Pharmaceuticals Co. Ltd** to **Shandong Anxin Pharmaceutical Co Ltd.** Firm has submitted reference for relevant change.	Complied

	Ltd. Clarify the title of manufacturer along with supportive documents.		

Later on firm submitted cross reference of same formulation (Piperacillin + Tazobactum 2gm/0.25g) applied by M/s Heathtek Pvt Ltd, manufactured at same site i.e M/s Stallion Pharmaceuticals Pvt Ltd. Lahore, approved in 308th meeting of Registration Board. The stability data was submitted for same stability batches as submitted in previous application and Drug substance source was also 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**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals PVT, LTD. 581-Sundar Industrial Estate, Lahore.

994.	Name, address of Applicant / Marketing Authorization Holder	SURGE LABORATORIES (PVT.) LTD. Head Office: 5th Floor, Commerce Centre, Hasrat Mohani Road, Karachi. Telephone: UAN 111-742-762 E-mail address: info@surgelaboratories.com
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals PVT, LTD. 581-Sundar Industrial Estate, Lahore Tel: +92 42 35297647-48
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24971 dated 02/09 /2022
	Details of fee submitted	PKR 75,000/- dated 16/06/2022
	The proposed proprietary name / brand name	Torpicillin IV 4.5g Powder for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin Sodium eq. to Piperacillin….4.0g Tazobactam Sodium eq. to Tazobactam…0.5g
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Carbapenems
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	1 vial of Powder for Injection + 2 ampoules of 10ml Sterile Water for Injection in a single pack
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Product Piperacillin / Tazobactam 4.0 g / 0.5 g Powder for solution for infusion IV is registered and being marketed by Wockhard Ash Road North, Wrexham Industrial Estate, Wrexham LL 13 9UF

	For generic drugs (me-too status)	Product TANZO 4.5g Injection (Piperacillin + Tazobactam) (039439) is registered and being marketed by M/s. Bosch Pharmaceuticals Pvt. Ltd (Pakistan)
	GMP status of the Finished product manufacturer	GMP Certificate granted based on inspection dated 02/10/2020 valid for 2 years
	Name and address of API manufacturer.	**M/s Qilu Tianhe Pharmaceuticals Co. Ltd** 849, Dongjia Town, Licheng District, Jinan, Shandong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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 Piperacillin + Tazobactam 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 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 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (HF7001D1, HF7002D2, HF7003D3)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tanzo Sterile Dry Powder Injection 4.5g (Piperacillin + Tazobactam) is registered and being marketed by M/s Bosch Pakistan Limited, by performing quality tests (Description, Identification, pH, water content, Reconstitution time, Endotoxin test, Sterility test and 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 Qilu Tianhe Pharmaceuticals Co. Ltd** 849, Dongjia Town, Licheng District, Jinan, Shandong, China
API Lot No.	KA1007150016, KA1007150022
Description of Pack	1 glass vial of Powder for Injection + 2 ampoules of 10ml Sterile Water for

(Container closure system)	Injection in a single pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	P5001	P5002	P5003
Batch Size	8600 vials	8600 vials	10,630 vials
Manufacturing Date	03-2015	03-2015	04-2015
Date of Initiation	16-04-2015	16-04-2015	04-06-2015
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No 2018001issued by Centre for Evaluation & Certificate of Shandong Food & Drug Administration valid till 24/07/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice no. SL-150202-Z dated 04-02-2015 duly attested by Assistant Director, DRAP, Lahore on 09-02-2015were provided. Total quantity 100Kg.
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 Assessor (DD PEC-XX):

Sr.#	Observation	Observation	Remarks
1.	Contract manufacturing agreement provided dated 01.04.2022 between M/s Stallion Pharmaceuticals Pvt, Ltd and M/s Nabiqasim Industries Pvt, Ltd instead of M/s Surge Laboratories (Pvt.) Ltd.	Contract manufacturing agreement between M/s Stallion Pharmaceuticals Pvt, Ltd and M/s Surge Laboratories (Pvt.) Ltd has been provided dated 31.12.2021.	Complied
2.	Submit valid GMP certificate/inspection report of contact manufacturer i.e M/s Stallion Pharmaceuticals Pvt, Ltd 581-Sundar Industrial Estate, Lahore.	GMP certificate based on inspection dated 20.09.2022, provided valid for 2 years.	Complied
3.	Submit approval letter for relevant section i.e Penicillin	Section approval letter dated 06.02.2014 submitted	Complied

	dry powder injection from CLB granted to manufacturer.	wherein Dry Powder Injection (Penicillin) was approved by CLB.	
4.	Mention correct pharmacotherapeutic group and ATC code	Pharmacotherapeutic group was corrected as Antibacterials for systemic use (Penicillin and Beta lactamase inhibitor)	Complied
5.	Title of Drug substance manufacturer mentioned on GMP certificate as **M/s Qilu Tianhe Pharmaceuticals Co. Ltd** while tile of drug substance manufacturer mentioned on rest of documents as **Shandong Anxin Pharmaceutical Co Ltd.** Clarify the title of manufacturer along with supportive documents.	Company name/title has been changed from **M/s Qilu Tianhe Pharmaceuticals Co. Ltd** to **Shandong Anxin Pharmaceutical Co Ltd.** Firm has submitted reference for relevant change.	Complied

Later on firm submitted cross reference of same formulation (Piperacillin + Tazobactum 4gm/0.5g) applied by M/s Heathtek Pvt Ltd, manufactured at same site i.e M/s Stallion Pharmaceuticals Pvt Ltd. Lahore, approved in 308th meeting of Registration Board. The stability data was submitted for same stability batches as submitted in previous application and Drug substance source was also 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**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals PVT, Ltd. 581-Sundar Industrial Estate, Lahore.

Deferred cases:

995.	**Name, address of Applicant / Marketing Authorization Holder**	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Evidence of approval of manufacturing facility	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26862 Date: 22/9/2022
	Details of fee submitted	PKR 30000 dated: 16-09-2022 . SLIP No. 003359682193

	The proposed proprietary name / brand name	**BRIPROFEN 200 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Ibuprofin …… 200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's, 20's,30's,100's,200's Blister (1000's Jar Pack)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	**Brand Name:** Pando (200mg) Tablet **Registration holder:** M/s Efroze Pharma(Pvt) Ltd , Karachi. **Registration Number:** 012062
	Name and address of API manufacturer.	**Ibuprofen (BP) :** M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months. **(Batch No. ZIBU11-001, ZIBU11-002, ZIBU11-003)**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have not been established/submitted with innovator Product, **but with Brufen 200 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi.** **CDP has been performed against the same brand that is** Brufen 200 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi **instead of Innovator / Reference Product** in

		Acid media (0.1N HCl),), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted **report of verification studies of analytical method (BP)** of drug substance. Firm has submitted report of verification of analytical method (USP) for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**		
API Lot No.	**API batch No. Zibu21-029**		
Description of Pack (Container closure system)	10's / Jar Pack Alu-PVC Blister Pack in unit carton with leaflet		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 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-B-1	T-B-2	T-B-3
Batch Size	1086 Tablets	1086 Tablets	1086 Tablets
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	03-05-2021	03-05-2021	03-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not required.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	For march 2021 while the stability is initiated in May 2021.
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.**

Evaluation by PEC:

1. GMP certificate of API manufacturer is issued on 22-05-2019.
2. Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted
3. Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.
4. Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms
5. Detail of equipment's/machinery as used in Product Development if not submitted.
6. Product Assay method as mentioned in Product Development is different from the one specified in (USP).
7. Specificity Method and test reports are not submitted for Drug Product.

8. %RSD is not calculated for tests performed for Drug Product analytical method verification.
9. In BMR check points include i.e. average tablet size to be 460mg, and target weight is also 460mg while the Tablet is of 200mg.
10. Chromatograms submitted along with stability data sheets in Briprofin 200mg tablets, date of data processing/acquiring is mentioned as 11-03-2021 while the stability is initiated in May 2021.

Decision of 323rd meeting of RB : Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Updated submission:

Sr No	Observation	Reply	Remarks
1.	GMP certificate of API manufacturer is issued on 22-05-2019.	*API manufacturer has applied for renewal of GMP. Copy of valid DML is attached.*	Submitted copy of DML is valid till 14.06.2021. updated GMP status is still required
2.	Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted	Analytical method verification of API from Drug product manufacturer is provided	Analytical method verification report/test results from Drug Substance manufacturer yet to be provided
3.	Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.	Detail of excipients along with specifications and compatibility studies is provided	Complied
4.	Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms	As weight of API is greater than 25mg so the weight variation is applied which is the parameter of uniformity of dosage unit as per USP. In stability report weight variation is performed and results are mentioned.	Justified
5.	Detail of equipment's/machinery as used in Product Development if not submitted	Submitted	Complied
6.	Product Assay method as mentioned in Product Development is different from the one specified in USP.	Product Assay method is same as specified in USP. However for record purpose method is attached.	Verified.
7.	Specificity Method and test reports are not submitted for Drug Product.	Verification Method and test reports are provided wherein specificity parameter was not provided	Not Complied
8.	%RSD is not calculated for tests performed for Drug Product analytical method verification.	Analytical method verification study is provided wherein %RSD is mentioned.	Verified
9.	In BMR check points include i.e. average tablet size to be 460mg, and target weight is also 460mg while the Tablet is of 200mg.	*Production weight of Briprofen 200mg tablet is 460mg and its average weight is*	Justified

		also obtained in 460mg range. Selected check points/parameters are for Briprofen 200mg tablet.	
10.	Chromatograms submitted along with stability data sheets in Briprofin 200mg tablets, date of data processing/acquiring is mentioned as 11-03-2021 while the stability is initiated in May 2021	*Format of date on HPLC chromatograms was MM.DD.YY. Stability study was initiated in May 2021 and 6 months stability was completed on November 2021 and was tested on 3rd of Nov 2021. As the format of date on HPLC system is MM.DD.YY that's why date of data processing/acquiring shown as 11.03.2021.*	Justified
Decision: Deferred for submission of Analytical Verification study/test reports of Drug Product including specificity parameter to be provided from Drug Product manufacturer.			

996.	**Name, address of Applicant / Marketing Authorization Holder**	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Evidence of approval of manufacturing facility	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26861 Date: 22/9/2022
	Details of fee submitted	PKR 30000 dated: 16-09-2022 . SLIP No. 0137541252
	The proposed proprietary name / brand name	**BRIPROFEN 400 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Ibuprofin …… 400mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's, 20's,30's,100's,200's Blister (1000's Jar Pack)

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved, (Ibuprofin 400mg by The Boots Company PLC 1 Thane Road West Nottingham NG2 3AA)
	For generic drugs (me-too status)	**Brand Name:** Zafen (400mg) Tablet **Registration holder:** M/s Xenon Pharma , Lahore. **Registration Number:** 050650
	Name and address of API manufacturer.	**Ibuprofen (BP) :** M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 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. **(Batch No. ZIBU11-001, ZIBU11-002, ZIBU11-003)**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have not been established/submitted with innovator Product, **but with Brufen 400 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi.** **CDP has been performed against the same brand that is** Brufen 400 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi **instead of Innovator / Reference Product** in Acid media (0.1N HCl),), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted **report of verification studies of analytical method (BP)** of drug substance. Firm has submitted report of verification of analytical method (USP) for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
API Lot No.	**API batch No. Zibu21-029**

Description of Pack (Container closure system)	10's / Jar Pack Alu-PVC Blister Pack in unit carton with leaflet		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 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-B-1	T-B-2	T-B-3
Batch Size	1162 Tablets	1162 Tablets	1162 Tablets
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	05-05-2021	05-05-2021	05-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not required.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms, Raw data sheets, summary data sheets are submitted only at **0 months (May 2021)**
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.**

Evaluation by PEC:

1. GMP certificate of API manufacturer is issued on 22-05-2019.
2. Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted
3. Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.
4. Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms
5. Detail of equipment's/machinery as used in Product Development is not submitted.
6. Product Assay method as mentioned in Product Development is different from the one specified in (USP).
7. Specificity Method and test reports are not submitted for Drug Product.
8. %RSD is not calculated for tests performed for Drug Product analytical method verification.
9. Detail of excipients along with specifications is not submitted as the excipients used in Product development are different from the ones in innovator product.
10. Chromatograms, Raw data sheets, summary data sheets are submitted only at **0 months (May 2021).**

Decision of 323rd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Sr No	Observation	Reply	Remarks
1.	GMP certificate of API manufacturer is issued on 22-05-2019.	*API manufacturer has applied for renewal of GMP. Copy of valid DML is attached.*	Submitted copy of DML is valid till 14.06.2021. updated GMP status is still required

2.	Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted	Analytical method verification of API from Drug product manufacturer is provided	Analytical method verification report/test results from Drug Substance manufacturer yet to be provided
3.	Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.	Detail of excipients along with specifications and compatibility studies is provided	Complied
4.	Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms	As weight of API is greater than 25mg so the weight variation is applied which is the parameter of uniformity of dosage unit as per USP. In stability report weight variation is performed and results are mentioned.	Justified
5.	Detail of equipment's/machinery as used in Product Development if not submitted	Submitted	Complied
6.	Product Assay method as mentioned in Product Development is different from the one specified in USP.	Product Assay method is same as specified in USP. However for record purpose method is attached.	Verified.
7.	Specificity Method and test reports are not submitted for Drug Product.	Verification Method and test reports are provided wherein specificity parameter was not mentioned	Not complied
8.	%RSD is not calculated for tests performed for Drug Product analytical method verification.	Analytical method verification study is provided wherein %RSD is mentioned.	Verified
9.	Chromatograms, Raw data sheets, summary data sheets are submitted only at **0 months (May 2021).**	Chromatograms, Raw data sheets, summary data sheets are not provided against rest of the time points.	Not complied

Decision: Deferred for following reasons:

- **Analytical Verification study/test reports of Drug Product including specificity parameter to be provided from Drug Product manufacturer.**
- **Chromatograms, Raw data sheets, summary data sheets of stability data to be provided against each time points.**

997.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Pharmadic Laboratories (Pvt) Ltd, 16 KM, Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pharmadic Laboratories (Pvt) Ltd, 16 KM, Multan Road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020
	Evidence of approval of manufacturing facility	Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10710 dated 28-04-22
	Details of fee submitted	PKR30000 dated: 27.05.2022 bearing Deposit Slip No. 09713095356
	The proposed proprietary name / brand name	Darvin Forte 75mg/650mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCL … 75mg Paracetamol ….. 650mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Opioid & Non-Opioid Analgesic
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	1x 10's (Alu-PVC Blisters)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CLANDERON 75 mg / 650 mg , Aristo Pharma Iberia, Madrid Spain.
	For generic drugs (me-too status)	Tonoflex-P Forte (film coated) of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi
	Name and address of API manufacturer.	**Paracetamol (USP/BP):** M/s Saakh Pharma (Pvt) Ltd, Karachi. **GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022** **Certificate No. ZJ20170049** **Tramadol HCL USP :** M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical

		form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months for both API's namely **Paracetamol & Tramadol HCL USP .**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. **The F2 values are not found satisfactory.**
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Paracetamol (BP):** M/s Saakh Pharma (Pvt) Ltd, Karachi. **GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022** **Certificate No. ZJ20170049** **Tramadol HCL USP :** M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.		
API Lot No.	Paracetamol: ZPAR18-143 Tramadol HCL : TDH 0041019		
Description of Pack (Container closure system)	The proposed pack size of Darvin Forte Tablet is 1x10's in Alu—PVC Blister.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6,9,12,18,24(Months)		
Batch No.	ACTD-TR001	ACTD-TR002	ACTD-TR003

Batch Size	1000 TABLETS	1000 TABLETS	1000 TABLETS
Manufacturing Date	10,2019	10,2019	10,2019
Date of Initiation	10-10-2019	10-10-2019	10-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• **Not Provided**
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol (USP/BP):** M/s Saakh Pharma (Pvt) Ltd, Karachi. **GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022** **Certificate No. ZJ20170049** **Tramadol HCL USP :** M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Paracetamol (BP):** Not Required **Tramadol HCL USP :** **Not Provided**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Provided.**

Evaluation by PEC:

1. Evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board shall be submitted. As the applied formulation in reference regulatory authorities is approved as "uncoated" tablets while the applicant has applied as film coated tablets

Decision: Since the applied product is approved as "uncoated tablet" in reference regulatory authorities while the applicant has applied for film coated tablet. Therefore, Registration Board decided to defer the case for evidence of approval of applied formulation in reference regulatory authorities/agencies a "film coated tablet" which were declared/approved by the Registration Board in its 275th meeting.

Reply of the firm :

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

Sr. No	Observation	Reply	Remarks
1.	Provide certificate of analysis of relevant batch(es) of Drug Substance(s) (Paracetamol & Tramadol HCL) used in product development (By both Drug Substance and Drug Product manufacturer.	CoA are provided for different batches.	Not complied CoA to be provided for relevant batches. **The CoA of Tramadol HCl batch No TDH 0480218 has been provided instead of batch no TDH 0041019 which**

			was mentioned in import invoice.
2.	The Pharmaceutical equivalence studies and comparative dissolution Profile studies are not conducted with the innovator Product.	Pharmaceutical equivalence /CDP performed against the **Tonoflex-P Forte Tablet** 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi Batch No 001E	Pharmaceutical equivalence /CDP performed against established brand
3.	Documents for the procurement of API with approval from DRAP (in case of import) of DS **Tramadol HCL USP**	Copy of invoice provided No E002 dated 06.11.2019 , attested by DRAP Lahore confirming import of 200Kg Tramadol HCl Batch No **TDH 0041019**	Complied
4.	As per submitted data of comparative dissolution profile following points have been observed: **For Paracetamol:** Value of F2 factor is 46% in Buffer Acetate pH 4.5 Value of F2 factor is 38% in Phosphate Buffer pH 6.8 **For Tramadol HCl:** value of F2 factor is 44% in 0.1N HCL Value of F2 factor is 46% in Phosphate buffer pH 6.8 Please justify scientifically.	Rectified CDP report has been submitted with f2 values as follows **For Paracetamol:** Value of F2 factor is 53% in acid medium pH 1.2 Value of F2 factor is 52% in Buffer Acetate pH 4.5 Value of F2 factor is 53% in Phosphate Buffer pH 6.8 **For Tramadol HCl:** Value of F2 factor is 54% in 0.1N HCL Value of F2 factor is 67% in Buffer Acetate pH 4.5 Value of F2 factor is 55% in Phosphate buffer pH 6.8	The F2 values are found satisfactory.
5.	Specificity testing in Analytical method validation has not been performed for the applied Product.	Analytical method validation study has been performed including parameter Specificity.	Complied
6.	Analytical Method for related substances /impurities testing of DS Paracetamol (BP) the HPLC testing procedure/chromatographic conditions are different from the one as specified in BP	Analytical Method for related substances /impurities testing of DS Paracetamol (BP) has been submitted wherein HPLC testing procedure/chromatographic conditions are as per BP (2019)	Complied
7.	DS manufacturer of Paracetamol has followed analytical method for testing(Assay) of API of BP while the Drug Product manufacturer has tested by USP Specs. (The analytical method by DS	Drug Product manufacturer has tested Drug Substance (Paracetamol) as per BP. CoA has been provided.	Complied

	manufacturer is mentioned as BP but on COA of DS Assay is mentioned as USP)		
8.	The excipients being used are different from the ones used in Product Development of Innovator/Reference Product, therefore, provide compatibility studies protocol/method along with results.	Drug-Excipient compatibility study has been provided The binary study makes it clear that both API are compatible with all excipients	Complied
Decision: Deferred for following: • **Submission of CoA of relevant batch of Tramadol HCl i.e., TDH 0041019 as mentioned in import invoice.** • **Scientific justification for the results reported in CDP studies with acceptable f2 value, whereas previously firm had reported different results of f2 value which were not within acceptable range, while the firm has not made any formulation change.**			

d) Deferred cases:

Deferred case of 322nd meeting:

585.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Anzo D MR Capsule
	Diary No. Date of R& I & fee	Dy No. 2368 (PEC DRAP) Dated 17.10.2022 (duplicate) Rs: 50,000/- 22-12-2017
	Composition	Each modified release capsule contains: Diclofenac sodium…….75mg Omeprazole…….20mg
	Pharmacological Group	Anti-arthritis Anti-ulcer
	Type of Form	Form 5-D
	Finished Product Specification	Innovator's Specs.
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities.	EMA Approved Diotop 75 mg / 20 mg modified release hard capsules
	Me-too status	Not Applicable
	GMP status	GMP inspection conduced on 07/07/2022 Capsule (General & General Antibiotic) section approved.

STABILITY STUDY DATA		
Drug	Anzo D MR Capsule	
Name of Manufacturer	M/s The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.	
Manufacturer of API	Diclofenac Sodium MR pellets : M/s Alphamed Formulations Private Limited	Omeprazole delayed release pellets: M/s Alphamed Formulations Private Limited
API Lot No.	RD0149-017	8000201-010
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton	
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months	

	Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,3,6,9,12,18(months)		
Batch No.	20PD-271	20PD-272	20PD-273
Batch Size	2500 cap	2500 cap	2500 cap
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	26-10.2020	26-10.2020	26-10.2020
No. of Batches	03		
Date of Submission	10-01-2022 (Dy No. 57 PEC, DRAP)		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT FOR EXEMPTION			
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
S. No.	Documents To Be Provided	Status	
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product for Tapendol (Tapentadol) Tablets 75mg & 100mg on 11th March, 2019. Further, the said panel inspection report was discussed in 289th Drug Registration Board meeting held on 14th – 16th May 2019. The case was approved and the inspection report confirms following points: The HPLC software is 21CFR Compliant as per record available with the firm. Audit trail on the testing reports is available. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software. Related manufacturing area, equipment, personnel and utilities are GMP compliant.	
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Diclofenac sodium MR pellets 35%: Firm has submitted COA of Diclofenac sodium MR pellets 35% (Batch No. RD0149-017) from M/s ALPHAMED FORMULATIONS PRIVATE LIMITED. COA (Batch No. RD0149-017)) from M/s The Searle Company Limited is also submitted. Omeprazole Delayed release pellets 20%w/w: Firm has submitted COA of Omeprazole Delayed release pellets 20%w/w (Batch No. 8000201-010.) from M/s ALPHAMED FORMULATIONS PRIVATE LIMITED. COA (Batch No. 8000201-010.)) from M/s The Searle Company Limited is also submitted	
3.	Method used for analysis of API from both API Manufacturer & Finished Product manufacturer	Submitted	
4.	Stability study data of API from API manufacturer	Diclofenac sodium MR pellets 35%: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches Omeprazole Delayed release pellets 20%w/w: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches	
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. L.Dis.No:93420/TS/2022 by M/s ALPHAMED FORMULATIONS PRIVATE	

<table>
<tr><td></td><td></td><td>LIMITED issued by Drugs Control Administration Government of Telangana. The certificate is valid till 15-08-2023.
..</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Diclofenac sodium pellets 35%:
Firm has submitted import License dated 02-12-2019 confirming import of 5Kg Diclofenac sodium MR pellets 35% w/w from M/s ALPHAMED FORMULATIONS PRIVATE LIMITED for Batch # RD0149-017.

Omeprazole Delayed release pellets 20%w/w
Firm has submitted import License dated 02-12-2019 confirming import of 1.8Kg Omeprazole Delayed release pellets 20%w/w from M/s ALPHAMED FORMULATIONS PRIVATE LIMITED for Batch # 8000201-010.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Since there is only encapsulation of pellets carried out at FPP mfg site, no additional excipients are required hence compatibility studies are not performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has manufactured three stability batches of Anzo D MR Capsule and has submitted copy of complete batch manufacturing. Details are as under:
<table>
<tr><td colspan="3">Anzo D MR Capsule (75mg+20mg)</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Date</td></tr>
<tr><td>20PD-271</td><td>2500 capsules</td><td>October 2020</td></tr>
<tr><td>20PD-272</td><td>2500 capsules</td><td>October 2020</td></tr>
<tr><td>20PD-273</td><td>2500 capsules</td><td>October 2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted Comparative dissolution study of their product against Aristo 75/20 capsule :
<table>
<tr><td>Feature</td><td>Reference product</td><td>Product of M/s The Searle Company</td></tr>
<tr><td>Brand name</td><td>Aristo capsule 75mg + 20mg</td><td>Anzo D MR capsule</td></tr>
<tr><td>Batch No.</td><td>1394180100</td><td>20PD-271</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:

1. pH 1.2 HCl buffer (omeprazole)
2. pH 4.5 Acetate buffer (diclofenac sodium)
3. pH 6.8 Phosphate buffer (both API)
4. purified water (diclofenac sodium)

on the basis of similarity factor (f2) result i.e NLT 50 of dissolution profile of both API in test product and reference product, both products are similar.</td></tr>
</table>

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers.

Remarks of Evaluator:

Permission/approval for manufacturing omeprazole delayed release pellets from relevant DCA.
Analytical Method Validation studies to be submitted by the firm.
Justify selection of Aristo 75/20 capsule for conducting comparative dissolution profile. Give details of aforementioned brand i.e manufacturer, approval status etc
Whether omeprazole pellets are tested in acetate medium or not, its not clear in profile. Clarify the results/release profile of each API tested in different mediums and conclude results accordingly, in CDP report
Innovator (EMA approved) product is Each modified release capsule contains 75 mg diclofenac sodium (25 mg as gastro resistant pellets and 50 mg as prolonged release pellets) and 20 mg of omeprazole (gastro-resistant pellets) however MR pellets of diclofenac sodium used by the firm has to be clarified in this regard.
Method of analytical testing to be submitted from pellets manufacturer.
Drug excipient computability (carried out by pellets manufacturer) to be submitted.
Justification to be provided for selection of acceptance criteria of dissolution (Q value, dissolution time, sampling time and medium etc)

Firm has submitted reply against above mentioned shortcomings (dated 08.11.2022) which is found unsatisfactory.

Decision: Registration Board deferred the application for above mentioned shortcomings.

Sr.#	Observation	Reply	Remarks
	Permission/approval for manufacturing omeprazole delayed release pellets from relevant DCA.	Firm has submitted copy of GMP certificate No. L.Dis.No. 4073/stores/2020 to M/s ALPHAMED FORMULATIONS PRIVATE LIMITED dated 20.11.2020 issued by Drugs Control Administration Government of Telangana. The certificate is valid till 20-11-2023.	Complied
	Analytical Method Validation studies to be submitted by the firm.	submitted	Complied
	Justify selection of Aristo 75/20 capsule for conducting comparative dissolution profile. Give details of aforementioned brand i.e manufacturer, approval status etc	Aristo 75/20 capsule is enlisted in Nationally Authorized Medicinal Product by EMA , member state where product is authorized is Germany (DE).	Complied

	Whether omeprazole pellets are tested in acetate medium or not, its not clear in profile. Clarify the results/release profile of each API tested in different mediums and conclude results accordingly, in CDP report	We have performed CDP in guidance of WHO technical report series No 992, 2015 as follows: "for delayed-release product dissolution test in acid medium (pH 1.2) for 2 hours followed by dissolution in pH 6.8. Regarding CDP of MR diclofenac sodium pellets, firm clarified that due to enteric coated and prolonged release nature of pellets there is no significant release in Ph 1.2 therefore they used purified water instead fas per WHO technical report series No 992, 2015 as under: "Water may be considered as an additional medium, especially when the API is unstable in the buffered media to the extent that the data are unusable."	Complied
	Innovator (EMA approved) product is Each modified release capsule contains 75 mg diclofenac sodium (25 mg as gastro resistant pellets and 50 mg as prolonged release pellets) and 20 mg of omeprazole (gastro-resistant pellets) however MR pellets of diclofenac sodium used by the firm has to be clarified in this regard.	MR pellets of diclofenac sodium used by the firm are same as innovator product i.e: Each modified release capsule contains 75 mg diclofenac sodium (25 mg as gastro resistant pellets and 50 mg as prolonged release pellets)	Complied
	Method of analytical testing to be submitted from pellets manufacturer.	Submitted	Complied
	Drug excipient computability (carried out by pellets manufacturer) to be submitted.	Drug excipient computability studies submitted for both pellets (Diclofenac sodium and omeprazole) from pellets manufacturer	Complied
	Justification to be provided for selection of acceptance criteria of dissolution (Q value, dissolution time, sampling time and medium etc)	As described below	Complied

Reply:

This is in reference to query regarding "Justification to be provided for selection of acceptance criteria of dissolution (Q value, dissolution time, Sampling time and medium etc.,".

As the product is not available in any pharmacopoeia that is why We, The Searle Company Limited combine the both monographs available for different pellets i.e. Diclofenac delayed released pellets and Diclofenac Extended released pellets and design a criteria to make assure that the dissolution criteria should be able to quantify the release of delayed released pellets along with the prolong released pellets simultaneously. For further elaboration please find below the details in the table;

Time	**Delayed Released Pellets (i.e., 25mg)**	**Extended Released Pellets (i.e., 50mg)**	**Total (Delayed Released Pellets + Extended Released Pellets) (i.e., 75mg)**	**Proposed Limit**
1 Hr	75% (Q) of 25mg = 18.75mg	Minimum 10% of 50mg = 5mg	23.75 mg of 75mg = 31.6%	NLT 25%
5 Hr	75% (Q) of 25mg = 18.75mg	55% of 50mg = 27.5mg	46.25mg of 75mg = 61%	60%±10% i.e.(50 – 70)%
10 Hr	75% (Q) of 25mg = 18.75mg	75% of 50mg = 37.5mg	56.25mg of 75mg = 75%	75%±10% (65 – 85)%
16 Hr	75% (Q) of 25mg = 18.75mg	85% of 50mg = 42.5mg	61.25mg of 75mg = 81%	NLT 75%
24 Hr	75% (Q) of 25mg = 18.75mg	-	-	NLT 80%

Decision of 324th meeting:

Deferred for following:

- Review of applied formulation against the innovator product for clarification regarding the Diclofenac sodium pellets, whether both modified and delayed release pellets were used or only modified release pellets.
- Justification for the applied pharmacological group.

Reply:

- Firm has submitted CoA of MR Diclofenac sodium pellets from pellet manufacturer i.e M/s ALPHAMED FORMULATIONS PRIVATE LIMITED confirming proportion of both delayed release pellets and prolonged release pellets in formulation.
- Firm has submitted reference of WHO ATC code i.e **M01AB55** which justified mentioned pharmacotherapeutic group.

Decision: Approved

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

Registration applications of newly granted DML or New section (Human)
New Section:
M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
CLB in its 279th meeting held on 18th February 2021, has considered and approved the grant of following additional section/facility:

- **Dry Powder for Injection (Cephalosporin) New.**

998.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32619 dated 14.11.2022
	Details of fee submitted	PKR 30,000/- dated 12.10.2022
	The proposed proprietary name / brand name	**Jaspime 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine equivalent to Cefepime ……. 1000mg
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 1g powder for solution for injection Bristol-Myers Squibb Company Princeton, NJ 08543 USA
	For generic drugs (me-too status)	Maxum 1.0gm Injection Curexa Health Pvt LTD, a subsidiary of Highnoon Laboratories Reg. No. 090509

	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 26.10.2020 valid till 25/10/2022. New Section Approval granted on 12-03-2021(Dry Powder For Injection Cephalosporin) .
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,B,C,D,E&F & 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 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(40003FK86D-A, 40004FK86D-A and 40005FK86D-A)
	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 brand that is Maxum 1.0gm Injection Curexa Health Pvt LTD, Batch No 2180120 by performing quality tests (Identification, Assay, BET, sterility test, Ph (after reconstitution), particulate matter, diluent volume etc against **Jaspime injection 1.0g (Batch No KI-01)**
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China
API Lot No.	1011AJ89DB

Description of Pack (Container closure system)	15ml glass vial with fluorobutyl rubber stopper		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	LH 01	LH 02	LH 03
Batch Size	100Vials	100Vials	100Vials
Manufacturing Date	11-10-2021	11-10-2021	11-10-2021
Date of Initiation	28-10-2021	28-10-2021	28-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
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).	Invoice NO JTRF210911-MQ Verified by DRAP Lahore 14373/204DRAP Dated 24-09-2021.wherein Cefepime HCl with L-Arginine 1000gm has been imported Batch No 1011AJ89DB.
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 (AD-PEC[XX]):

1.6.5 Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.
3.2.S.4 CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)
3.2.S.4 Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.
3.2.S.4 The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added reference product (USFDA approved) to control the pH of the constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) 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 / API manufacture

3.2.P.8 In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products_en.pdf)
3.2.P.8 In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product
3.2.P.1 Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.
3.2.P.2 Perform suitability testing of proposed container closure system (Ph.Eur type II glass vial) as per pharmacopeia.
3.2.P.2 Justify selection of that particular comparator product.
3.2.P.2 Compatibility studies of drug product with diluent is not provided.
3.2.P.3 Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ Master formula.

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

Sr.#	Observations	Reply	Remarks
1.	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by China Food and Drug Administration (No SD20180660) valid till 08.02.2023 is provided	Complied
2.	CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)	CoA of Drug substance as per USP is submitted from Drug product manufacturer wherein assay result is mentioned as **893 ug/mg** (anhydrous basis) which falls within limit (**825ug/mg to 911ug/mg)** as per USP. The assay result obtained as 519ug/mg (on as is basis)	Complied
3.	Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.	CoA of Drug substance as per USP (both from Drug Product manufacturer and Drug Substance manufacturer) wherein crystallinity and water determination tests were mentioned	Complied
4.	The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added in reference product (USFDA approved) to control the pH of the	The ratio of L Arginine and cefepime activity	Complied

	constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.	has been provided as under: Sterile arginine : cefepime activity 0.707 : 1 In total quantity (cefepime HCl with L arginine) of 1.707g, quantity of L arginine used = 0.707g (i.e 707mg/g or 39.94%)	
5.	Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) 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 / API manufacture	CoA of Drug substance to be provided (from Drug product manufacturer) already provided CoA is of batch No **1011A18906**	CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer
6.	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted with WFI) for period of 24 hours (at 30˚C ± 2˚C / 65% ± 5%RH) is provided, for all three stability batches	Complied
7.	In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.	Stability study report is provided wherein pharmacopoeial quality parameters like BET, sterility test, water determination and uniformity of dosage unit, were tested	Complied
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product	Provided	Complied
9.	Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.	**Sterile water for injection** is used for reconstitution. Details mentioned below: **Aquakan 5ml Reg No:111993 by Jaskan pharmaceutical**	Complied
10.	Perform suitability testing of proposed container closure system (*Ph.Eur* type II glass vial) as per pharmacopeia	Tests and specifications of Type II glass vial is provided (including pharmacopoeial tests of hydrolytic resistance i.e glass surface test and glass grain tests)	Complied

11.	Justify selection of that particular comparator product. Moreover pharmaceutical equivalence study against Jaspime 500mg injection has not been performed (instead Jaspime 1000mg injection was used against Cefstar 500 mg Injection)	Innovator product is not available in Pakistan hence **Maxum 1.0gm Injection** Curexa Health Pvt LTD, Batch No 2180120 was selected for pharmaceutical equivalence study.	Justified
12.	Compatibility studies of drug product with diluent is not provided.	No any incompatibility is recorded with diluent.	
13.	Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ master formula.	Calculation provided including assay result, LOD and Arginine content.	Calculation regarding potency adjustment (salt factor) is not provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.

Decision: Deferred for following reasons:

- **CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer**
- **Calculation regarding potency adjustment (salt factor) is to be provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.**

999.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32618 R&1 DRAP dated 14th Nov.2022
	Details of fee submitted	PKR 30,000/- dated 12.10.2022
	The proposed proprietary name / brand name	**Jaspime 500mg injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains:

		Cefepime HCl with L-Arginine equivalent to Cefepime ……. 500mg
	Pharmaceutical form of applied drug	Dry powder for solution for Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 0.5g powder for solution for injection Bristol-Myers Squibb Company Princeton, NJ 08543 USA USFDA approved
	For generic drugs (me-too status)	Cefstar 500 mg Injection By Barrett Hodgson Pakistan Pvt LTD Reg. No. 030953
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 26.10.2020 valid till 25/10/2022. New Section Approval granted on 12-03-2021(Dry Powder For Injection Cephalosporin) .
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 Dongjia Town Licheng District, Jinan , Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity A,B,C,D,E&F & 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 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(40003FK86D-A, 40004FK86D-A and 40005FK86D-A)
	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 comparator product Cefstar 500 mg Injection By Barrett Hodgson Pakistan Pvt Ltd Batch No. C5824 by performing quality tests (Identification, Assay, BET, sterility test, Ph (after reconstitution), particulate matter, diluent volume etc against **Jaspime injection 1.0g (Batch No LI-01)**
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China		
API Lot No.	1011AJ89DB		
Description of Pack (Container closure system)	15ml glass vial with fluorobutyl rubber stopper		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LI 01	LI 02	LI 03
Batch Size	100 Vials	100 Vials	100 Vials
Manufacturing Date	11-10-2021	11-10-2021	11-10-2021
Date of Initiation	28-10-2021	28-10-2021	28-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
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).	Invoice NO JTRF210911-MQ Verified by DRAP Lahore 14373/204DRAP Dated 24-09-2021.wherein Cefepime HCl with L-Arginine 1000gm has been imported Batch No 1011AJ89DB
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 (AD-PEC[XX]):

.6.5 Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.

3.2.S.4 CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)

3.2.S.4 Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.

3.2.S.4 The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added reference product (USFDA approved) to control the pH of the constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) 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 / API manufacture

3.2.P.8 In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products_en.pdf)

3.2.P.8 In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.

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

3.2.P.1 Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.

3.2.P.2 Perform suitability testing of proposed container closure system (Ph.Eur type II glass vial) as per pharmacopeia.

3.2.P.2 Justify selection of that particular comparator product.

3.2.P.2 Compatibility studies of drug product with diluent is not provided.

3.2.P.3 Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ Master formula.

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

Sr.#	Observations	Reply	Remarks
1.	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by China Food and Drug Administration (No SD20180660) valid till 08.02.2023 is provided	Complied
2.	CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)	CoA of Drug substance as per USP is submitted from Drug product manufacturer wherein assay result is mentioned as **893 ug/mg** (anhydrous basis) which falls within limit (**825ug/mg to 911ug/mg)** as per USP. The assay result obtained as	Complied

		519ug/mg (on as is basis)	
3.	Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.	CoA of Drug substance as per USP (both from Drug Product manufacturer and Drug Substance manufacturer) wherein crystallinity and water determination tests were mentioned	Complied
4.	The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added in reference product (USFDA approved) to control the pH of the constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.	The ratio of L Arginine and cefepime activity has been provided as under: Sterile arginine : cefepime activity 0.707 : 1 In total quantity (cefepime HCl with L arginine) of 1.707g, quantity of L arginine used = 0.707g (i.e 707mg/g or 39.94%)	Complied
5.	Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) 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 / API manufacture	CoA of Drug substance to be provided (from Drug product manufacturer) already provided CoA is of batch No **1011A18906**	CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer
6.	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	In use stability data (reconstituted with WFI) for period of 24 hours (at 30˚C ± 2˚C / 65% ± 5%RH) is provided, for all three stability batches	Complied
7.	In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.	Stability study report is provided wherein pharmacopoeial quality parameters like BET, sterility test, water determination and uniformity of dosage unit, were tested	Complied
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product	Provided	Complied
9.	Provide information including type of diluent, its composition, quantity or volume, specifications	**Sterile water for injection** is used for reconstitution.	Complied

	Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.	Details mentioned below: **Aquakan 5ml** **Reg No:111993** **by Jaskan pharmaceutical**	
10.	Perform suitability testing of proposed container closure system (*Ph.Eur* type II glass vial) as per pharmacopeia	Tests and specifications of Type II glass vial is provided (including pharmacopoeial tests of hydrolytic resistance i.e glass surface test and glass grain tests)	Complied
11.	Justify selection of that particular comparator product. Moreover pharmaceutical equivalence study against Jaspime 500mg injection has not been performed (instead Jaspime 1000mg injection was used against Cefstar 500 mg Injection)	Innovator product is not available in Pakistan hence **Cefstar 500mg Injection** by Barrett Hodgson Pvt Ltd, **Batch No C5824** was selected for pharmaceutical equivalence study. Moreover, revised/corrected pharmaceutical equivalence study is submitted by performing quality tests against **Jaspime injection 500mg (Batch No LI-01)**	Justified
12.	Compatibility studies of drug product with diluent is not provided.	No any incompatibility is recorded with diluent.	
13.	Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ master formula.	Calculation provided including assay result, LOD and Arginine content.	Calculation regarding potency adjustment (salt factor) is not provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.

Decision: Deferred for following reasons:

- **CoA of Drug substance of Batch No 1011AJ89DB, to be provided from Drug Product manufacturer**

- **Calculation regarding potency adjustment (salt factor) is to be provided. Moreover, batch formula/master formula to be updated for clarification of quantity used after potency adjustment.**

Agenda of Evaluator PEC-XXI

Agenda Item No. 01: Routine Applications of Human Drugs Locally Manufactured Applied on Form - 5F

997.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 790 dated 10th January 2022.
	Details of fee submitted	PKR 75,000/- dated 08 December, 2021
	The proposed proprietary name / brand name	TIGLOZIN Tablet 5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ertugliflozin L Pyroglutamic acid equivalent to Ertugliflozin…5mg (Innovator's Specs.)
	Pharmaceutical form of applied drug	Light pink colored, spindle shaped coated tablet engraved NQ on one side while other side engraved bisect line.
	Pharmacotherapeutic Group of (API)	A10BK04 Drugs used in diabetes, Sodium glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	10's, 14's, 20's, 28's & 30's tablets
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	STEGLATRO™ (Ertugliflozin) tablets, for oral use by Merck Sharp & Dohme Corp., (USFDA Approved).
	For generic drugs (me-too status)	Ertuvia 5mg Tablet (Reg. No. 110362) of M/s Ferozsons Laboratories Limited.

	GMP status of the Finished product manufacturer	GMP Certificate granted based on Inspection conducted on 19th September 2020, issued for Tablet (General & Antibiotic), Capsule (General & Cephalosporin), Dry Powder for Suspension (General Antibiotic & Cephalosporin), Oral Liquid (Syrup) (Non-Antibiotic & Antibiotic), Cream / Ointment / Lotion (Non-Antibiotic & Antibiotic & Steroids), Eye & Ear Drops (Non-Antibiotic & Antibiotic & Steroids), Liquid Enema (General), Sachet (General), Small Volume Lyophilized Injectable (Non-Antibiotic, Antibiotic), Gel & Tablet (Hormones) Sections.
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province-123000, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Ertugliflozin is present as per In-house (Manufacturer's) specifications. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	API 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: 20150328, 20150406 and 20150513.
	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 mediums) 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 STEGLATRO Tablet 5mg (Ertugliflozin) of M/s Merck Sharp & Dohme Ltd. by performing quality tests (Description, Identification, Dissolution and Assay). CDP have been performed against the same brand

		i.e. STEGLATRO Tablet 5mg (Ertugliflozin) of M/s Merck Sharp & Dohme Ltd., in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 85% of both test and reference samples showed release within 15 minutes.
	Analytical method validation / verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co., Ltd.		
API Lot No.	IG-20210126-D01-IG06-01		
Description of Pack (Container closure system)	Alu - Alu blister of 10's, 14's, 20's, 28's & 30's tablets packed in unit carton.		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	435DS01	435DS02	435DS03
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	07 - 2021	07 - 2021	07 - 2021
Date of Initiation	30-07-2021	30-07-2021	30-07-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	The Firm have submitted information of 07 Products approved previously with stability data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Liaoning Fuxin Management Committee for Flouride Industrial Development Zone, China valid till 23/08/2023 along with copy of Manufacturing License.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. HN20210326-A dated 28/04/ 2021 duly attested by Assistant Director, DRAP, Karachi on 11-06-2021 has been provided.
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:
Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months vide Dy. No. 4534 dated 17 FEB 2022.

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.**		
998.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 791 dated 10th January 2022.
	Details of fee submitted	PKR 75,000/- dated 08 December, 2021
	The proposed proprietary name / brand name	**TIGLOZIN Tablet 15mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ertugliflozin L Pyroglutamic acid equivalent to Ertugliflozin…15mg (Innovator's Specs.)
	Pharmaceutical form of applied drug	Reddish pink colored, spindle shaped coated tablet engraved NQ on one side while other side engraved bisect line.
	Pharmacotherapeutic Group of (API)	A10BK04 Drugs used in diabetes, Sodium glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	10's, 14's, 20's, 28's & 30's tablets
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	STEGLATRO™ (Ertugliflozin) tablets, for oral use by Merck Sharp & Dohme Corp., (USFDA Approved).
	For generic drugs (me-too status)	Ertuvia 15mg Tablet (Reg. No. 110363) of M/s Ferozsons Laboratories Limited.
	GMP status of the Finished product manufacturer	GMP Certificate granted based on Inspection conducted on 19th September 2020, issued for Tablet (General & Antibiotic), Capsule (General & Cephalosporin), Dry Powder for Suspension (General Antibiotic & Cephalosporin), Oral Liquid (Syrup) (Non-Antibiotic & Antibiotic), Cream / Ointment / Lotion (Non-Antibiotic & Antibiotic & Steroids), Eye & Ear Drops (Non-Antibiotic & Antibiotic & Steroids), Liquid

		Enema (General), Sachet (General), Small Volume Lyophilized Injectable (Non-Antibiotic, Antibiotic), Gel & Tablet (Hormones) Sections.
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province-123000, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Ertugliflozin is present as per In-house (Manufacturer's) specifications. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	API 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: 20150328, 20150406 and 20150513.
	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 mediums) 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 STEGLATRO Tablet 15mg (Ertugliflozin) of M/s Merck Sharp & Dohme Ltd. by performing quality tests (Description, Identification, Dissolution and Assay). CDP have been performed against the same brand i.e. STEGLATRO Tablet 15mg (Ertugliflozin) of M/s Merck Sharp & Dohme Ltd., in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 85% of both test and reference samples showed release within 15 minutes.
	Analytical method validation / verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA			
Manufacturer of API	Fuxin Long Rui Pharmaceutical Co., Ltd.		
API Lot No.	IG-20210126-D01-IG06-01		
Description of Pack (Container closure system)	Alu - Alu blister of 10's, 14's, 20's, 28's & 30's tablets packed in unit carton.		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	436DS01	436DS02	436DS03
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	07 - 2021	07 - 2021	07 - 2021
Date of Initiation	30-07-2021	30-07-2021	30-07-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The Firm have submitted information of 07 Products approved previously with stability data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Liaoning Fuxin Management Committee for Flouride Industrial Development Zone, China valid till 23/08/2023 along with copy of Manufacturing License.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. HN20210326-A dated 28/04/ 2021 duly attested by Assistant Director, DRAP, Karachi on 11-06-2021 has been provided.
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: Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months vide Dy. No. 4535 dated 17 FEB 2022.

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.**

999.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD.

		17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2809 dated 28th January 2022.
	Details of fee submitted	PKR 75,000/- dated 08 December, 2021
	The proposed proprietary name / brand name	**TIGLOZIN-S Tablet 5mg/100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ertugliflozin L Pyroglutamic acid equivalent to Ertugliflozin…5mg Sitagliptin Phosphate Monohydrate equivalent to Sitagliptin….100mg (Innovator's Specs.)
	Pharmaceutical form of applied drug	Light brown colored, oblong shaped coated tablet engraved NQ on one side while other side engraved bisect line
	Pharmacotherapeutic Group of (API)	A10BD24 Drugs used in diabetes, Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	10's, 14's, 28's & 30's tablets
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	STEGLUJAN™ 5/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp., (USFDA Approved).
	For generic drugs (me-too status)	Ertuvia-S Tablet 5/100mg (Reg. No. 110364) of M/s Ferozsons Laboratories Limited.
	GMP status of the Finished product manufacturer	GMP Certificate granted based on Inspection conducted on 19th September 2020, issued for Tablet (General & Antibiotic), Capsule (General & Cephalosporin), Dry Powder for Suspension (General Antibiotic & Cephalosporin), Oral Liquid (Syrup) (Non-Antibiotic & Antibiotic), Cream / Ointment / Lotion (Non-Antibiotic & Antibiotic & Steroids), Eye & Ear Drops (Non-Antibiotic & Antibiotic & Steroids), Liquid Enema (General), Sachet (General), Small Volume Lyophilized Injectable (Non-Antibiotic, Antibiotic), Gel & Tablet (Hormones) Sections.
	Name and address of API manufacturer.	Ertugliflozin L Pyroglutamic acid: Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma

<table>
<tr><td></td><td></td><td>Tu), Fuxin City, Liaoning Province-123000, China.

Sitagliptin Phosphate Monohydrate:
Zhejiang Yongtai Pharmaceutical Co. Ltd.
No. 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base, Linhai Zone, Linhai City, Zhejiang Province, 317016, 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 / validation, 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>Ertugliflozin L Pyroglutamic acid:
Monograph of Ertugliflozin L Pyroglutamic acid is present as per In-house (Manufacturer's) specifications. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Sitagliptin Phosphate Monohydrate:
Monograph of Sitagliptin Phosphate Monohydrate is present 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 (Impurity A, Impurity C, Any single unknown impurity, Total impurities, Heavy metal, Chiral purity R-isomer), Residual solvents, specifications, analytical procedures and its verification, 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>API 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.
<table><tr><th>Ertugliflozin L Pyroglutamic acid Batches</th><th>Sitagliptin Phosphate Monohydrate Batches</th></tr><tr><td>20150328, 20150406 and 20150513.</td><td>1827-0001-19010, 1827-0001-19011 and 1827-0001-19012.</td></tr></table></td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>The firm has submitted detail of manufacturers, description of manufacturing process and</td></tr>
</table>

		controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer mediums) 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 STEGLUJAN™ 5/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp. by performing quality tests (Description, Identification, Dissolution and Assay). CDP have been performed against the same brand i.e. STEGLUJAN™ 5/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 85% of both test and reference samples showed release within 15 minutes.
	Analytical method validation / verification of product	Method validation studies have been submitted including system suitability, specificity, linearity, range, accuracy, precision, and force degradation.

STABILITY STUDY DATA			
Manufacturer of API	Ertugliflozin L Pyroglutamic acid: Fuxin Long Rui Pharmaceutical Co., Ltd.		
	Sitagliptin Phosphate Monohydrate: Zhejiang Yongtai Pharmaceutical Co. Ltd.		
API Lot No.	Ertugliflozin L Pyroglutamic acid: IG-20210126-D01-IG06-01 Sitagliptin Phosphate Monohydrate: 1827-0001-20009		
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: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	439DS01	439DS02	439DS03
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	07 - 2021	07 - 2021	07 - 2021
Date of Initiation	16-07-2021	16-07-2021	16-07-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The Firm have submitted information of 07 Products approved previously with stability data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L Pyroglutamic acid: Copy of GMP certificate issued by Liaoning Fuxin Management Committee for Flouride Industrial Development Zone, China valid till 23/08/2023 along with copy of Manufacturing License. Sitagliptin Phosphate Monohydrate:

		Copy of GMP certificate issued by Medical and Chemical Industry Association valid till 28/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Ertugliflozin L Pyroglutamic acid: Copy of Invoice No. HN20210326-A dated 28/04/ 2021 duly attested by Assistant Director, DRAP, Karachi on 11-06-2021 has been provided. Sitagliptin Phosphate Monohydrate: Copy of Invoice No. 2020APE40538 dated 25/03/ 2020 duly attested by Assistant Director, DRAP, Karachi on 19-05-2020 has been provided.
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: Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months vide Dy. No. 4536 dated 17 FEB 2022.		
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.**		
1000.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan. Telephone: + (21) 32213886, 32633590, UAN 111-742-762 E-mail address: info@nabiqasim.com
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2943 dated 31st January 2022.

	Details of fee submitted	PKR 75,000/- dated 20th December, 2021.
	The proposed proprietary name / brand name	TIGLOZIN-S Tablet 15mg/100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ertugliflozin L Pyroglutamic acid equivalent to Ertugliflozin…15mg Sitagliptin Phosphate Monohydrate equivalent to Sitagliptin….100mg (Innovator's Specs.)
	Pharmaceutical form of applied drug	Brown colored, oblong shaped coated tablet engraved NQ on one side while other side engraved bisect line
	Pharmacotherapeutic Group of (API)	A10BD24 Drugs used in diabetes, Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	10's, 14's, 28's & 30's tablets
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	STEGLUJAN™ 15/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp., (USFDA Approved).
	For generic drugs (me-too status)	Ertuvia-S Tablet 15/100mg (Reg. No. 110365) of M/s Ferozsons Laboratories Limited.
	GMP status of the Finished product manufacturer	GMP Certificate granted based on Inspection conducted on 19th September 2020, issued for Tablet (General & Antibiotic), Capsule (General & Cephalosporin), Dry Powder for Suspension (General Antibiotic & Cephalosporin), Oral Liquid (Syrup) (Non-Antibiotic & Antibiotic), Cream / Ointment / Lotion (Non-Antibiotic & Antibiotic & Steroids), Eye & Ear Drops (Non-Antibiotic & Antibiotic & Steroids), Liquid Enema (General), Sachet (General), Small Volume Lyophilized Injectable (Non-Antibiotic, Antibiotic), Gel & Tablet (Hormones) Sections.
	Name and address of API manufacturer.	Ertugliflozin L Pyroglutamic acid: Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province-123000, China. Sitagliptin Phosphate Monohydrate: Zhejiang Yongtai Pharmaceutical Co. Ltd. No. 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base, Linhai Zone, Linhai City, Zhejiang Province, 317016, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug

<table>
<tr><td></td><td></td><td>product is submitted.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>Ertugliflozin L Pyroglutamic acid:
Monograph of Ertugliflozin L Pyroglutamic acid is present as per In-house (Manufacturer's) specifications. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Sitagliptin Phosphate Monohydrate:
Monograph of Sitagliptin Phosphate Monohydrate is present 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 (Impurity A, Impurity C, Any single unknown impurity, Total impurities, Heavy metal, Chiral purity R-isomer), Residual solvents, specifications, analytical procedures and its verification, 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>API 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.
<table><tr><th>Ertugliflozin L Pyroglutamic acid Batches</th><th>Sitagliptin Phosphate Monohydrate Batches</th></tr><tr><td>20150328, 20150406 and 20150513.</td><td>1827-0001-19010, 1827-0001-19011 and 1827-0001-19012.</td></tr></table></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 mediums) 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>Pharmaceutical Equivalence have been established against STEGLUJAN™ 15/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp. by performing quality tests (Description, Identification, Dissolution and Assay).

CDP have been performed against the same brand i.e. STEGLUJAN™ 15/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 85% of both test and reference samples showed release</td></tr>
</table>

		within 15 minutes.		
	Analytical method validation / verification of product	Method validation studies have been submitted including system suitability, specificity, linearity, range, accuracy, precision, and force degradation.		
STABILITY STUDY DATA				
Manufacturer of API		Ertugliflozin L Pyroglutamic acid: Fuxin Long Rui Pharmaceutical Co., Ltd.		
		Sitagliptin Phosphate Monohydrate: Zhejiang Yongtai Pharmaceutical Co. Ltd.		
API Lot No.		Ertugliflozin L Pyroglutamic acid: IG-20210126-D01-IG06-01 Sitagliptin Phosphate Monohydrate: 1827-0001-20009		
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: 06 Months Accelerated: 06 Months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		437DS01	437DS02	437DS03
Batch Size		1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date		07 - 2021	07 - 2021	07 - 2021
Date of Initiation		16-07-2021	16-07-2021	16-07-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The Firm have submitted information of 07 Products approved previously with stability data.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L Pyroglutamic acid: Copy of GMP certificate issued by Liaoning Fuxin Management Committee for Flouride Industrial Development Zone, China valid till 23/08/2023 along with copy of Manufacturing License. Sitagliptin Phosphate Monohydrate: Copy of GMP certificate issued by Medical and Chemical Industry Association valid till 28/06/2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Ertugliflozin L Pyroglutamic acid: Copy of Invoice No. HN20210326-A dated 28/04/ 2021 duly attested by Assistant Director, DRAP, Karachi on 11-06-2021 has been provided. Sitagliptin Phosphate Monohydrate: Copy of Invoice No. 2020APE40538 dated 25/03/ 2020 duly attested by Assistant Director, DRAP, Karachi on 19-05-2020 has been provided.		
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:

Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months vide Dy. No. 4537 dated 17 FEB 2022.

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.**

1001.	Name, address of Applicant / Marketing Authorization Holder	M/S HORIZON HEALTHCARE (PVT.) LTD. Plot No. 33, Sundar Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/S HORIZON HEALTHCARE (PVT.) LTD. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 402 dated 05th JAN 2022.
	Details of fee submitted	PKR 75,000/- dated 24 December, 2021.
	The proposed proprietary name / brand name	**Ertusit Tablet 5mg/100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ertugliflozin as L-Pyroglutamic Acid …5mg Sitagliptin as Phosphate …100mg (Innovator's Specs.)
	Pharmaceutical form of applied drug	Beige colored, almond shaped coated tablet
	Pharmacotherapeutic Group of (API)	A10BD24 Drugs used in diabetes, Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	STEGLUJAN™ 5/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp., (USFDA Approved).
	For generic drugs (me-too status)	Ertuvia-S Tablet 5/100mg (Reg. No. 110364) of M/s Ferozsons Laboratories Limited.
	GMP status of the Finished product manufacturer	GMP Certificate granted on 06-07-2020 (based upon evaluation conducted on 18-06-2020) issued for Tablet (General & Antibiotic), Capsule (General & Antibiotic) and Oral Liquid (General Sections.
	Name and address of API manufacturer.	Ertugliflozin L Pyroglutamic acid: Zhejiang TOP Medicine Co. Ltd.

<table>
<tr><td></td><td></td><td>88, South St. of South Lake Zhongguan, Deqing Zhejiang Province, P.R. China, 313220.

Sitagliptin Phosphate Monohydrate:
Zhejiang Yongtai Pharmaceutical Co. Ltd.
No. 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base, Linhai Zone, Linhai City, Zhejiang Province, 317016, 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 / validation, 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>Ertugliflozin L Pyroglutamic acid:
Monograph of Ertugliflozin L Pyroglutamic acid is present as per In-house (Manufacturer's) specifications. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

Sitagliptin Phosphate Monohydrate:
Monograph of Sitagliptin Phosphate Monohydrate is present 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 (Impurity A, Impurity C, Any single unknown impurity, Total impurities, Heavy metal, Chiral purity R-isomer), Residual solvents, specifications, analytical procedures and its verification, 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>API 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.

Ertugliflozin L-Pyroglutamic acid:

<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>20150328</td><td>06 Months</td><td>36 Months</td></tr>
<tr><td>20150406</td><td>06 Months</td><td>36 Months</td></tr>
<tr><td>20150513</td><td>06 Months</td><td>36 Months</td></tr>
</table>

Sitagliptin Phosphate:
<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
</table>
</td></tr>
</table>

		1827-0001-19010 | 06 Months | 36 Months 1827-0001-19011 | 06 Months | 36 Months 1827-0001-19012 | 06 Months | 36 Months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer mediums) 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 STEGLUJAN™ 5/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp. by performing quality tests (Description, Identification, Dissolution and Assay). CDP have been performed against the same brand i.e. STEGLUJAN™ 5/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 80% of both test and reference samples showed release within 15 minutes.
	Analytical method validation / verification of product	Method validation studies have been submitted including Verification of Assay Method, Specificity, Accuracy, Precision, Linearity concentration and Peak Range.

STABILITY STUDY DATA			
Manufacturer of API	Ertugliflozin L Pyroglutamic acid: Zhejiang TOP Medicine Co. Ltd.		
	Sitagliptin Phosphate Monohydrate: Zhejiang Yongtai Pharmaceutical Co. Ltd.		
API Lot No.	Ertugliflozin L Pyroglutamic acid: PF-20200601 Sitagliptin Phosphate Monohydrate: 1827-0001-21014		
Description of Pack (Container closure system)	Alu-Alu Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 09 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	ESL-001	ESL-002	ESL-003
Batch Size	2,500 Tab	2,500 Tab	2,500 Tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	27-09-2021	27-09-2021	28-09-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Firm has referred to onsite inspection report of their products EMPAZON 10mg Tablets / EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules / Dayzol 60mg Capsules (Dexlansoprazole) conducted on 1st June, 2021 and presented in 307th meeting of Registration Board held on 08-10th June , 2021.	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L Pyroglutamic acid: Copy of GMP certificate issued by Zhejiang Medical Center for Economic Development, China along with copy of License. Sitagliptin Phosphate Monohydrate: Copy of GMP certificate issued by Zhejiang Food and Drug Administration, China along with copy of License.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Ertugliflozin L Pyroglutamic acid: Copy of Invoice No. CF20210706 dated 05/08/ 2021 duly attested by Assistant Director, DRAP, Lahore on 25-08-2021 has been provided. Sitagliptin Phosphate Monohydrate: Copy of Invoice No. 21APE040413 dated 08/05/ 2021 duly attested by Assistant Director, DRAP, Lahore on 21-05-2021 has been provided.
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:

Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated) and 09 Months (Real Time) vide Dy. No. 3653 dated 08 FEB 2023.

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.**

1002.	Name, address of Applicant / Marketing Authorization Holder	M/S HORIZON HEALTHCARE (PVT.) LTD. Plot No. 33, Sundar Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/S HORIZON HEALTHCARE (PVT.) LTD. Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 403 dated 05th JAN 2022.
	Details of fee submitted	PKR 75,000/- dated 24 December, 2021.

	The proposed proprietary name / brand name	Ertusit Tablet 15mg/100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ertugliflozin as L-Pyroglutamic Acid …15mg Sitagliptin as Phosphate …100mg (Innovator's Specs.)
	Pharmaceutical form of applied drug	Brown colored, almond shaped coated tablet
	Pharmacotherapeutic Group of (API)	A10BD24 Drugs used in diabetes, Combinations of oral blood glucose lowering drugs.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	STEGLUJAN™ 15/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp., (USFDA Approved).
	For generic drugs (me-too status)	Ertuvia-S Tablet 15/100mg (Reg. No. 110365) of M/s Ferozsons Laboratories Limited.
	GMP status of the Finished product manufacturer	GMP Certificate granted on 06-07-2020 (based upon evaluation conducted on 18-06-2020) issued for Tablet (General & Antibiotic), Capsule (General & Antibiotic) and Oral Liquid (General Sections.
	Name and address of API manufacturer.	Ertugliflozin L Pyroglutamic acid: Zhejiang TOP Medicine Co. Ltd. 88, South St. of South Lake Zhongguan, Deqing Zhejiang Province, P.R. China, 313220. Sitagliptin Phosphate Monohydrate: Zhejiang Yongtai Pharmaceutical Co. Ltd. No. 1, 4th Donghai Avenue, Zhejiang Provincial Chemical and Medical Raw Material Base, Linhai Zone, Linhai City, Zhejiang Province, 317016, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Ertugliflozin L Pyroglutamic acid: Monograph of Ertugliflozin L Pyroglutamic acid is present as per In-house (Manufacturer's) specifications. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Sitagliptin Phosphate Monohydrate: Monograph of Sitagliptin Phosphate Monohydrate is present is as per USP specifications. The firm as

<table>
<tr><td></td><td></td><td>submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Impurity A, Impurity C, Any single unknown impurity, Total impurities, Heavy metal, Chiral purity R-isomer), Residual solvents, specifications, analytical procedures and its verification, 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>API 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.

Ertugliflozin L-Pyroglutamic acid:

<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>20150328</td><td>06 Months</td><td>36 Months</td></tr>
<tr><td>20150406</td><td>06 Months</td><td>36 Months</td></tr>
<tr><td>20150513</td><td>06 Months</td><td>36 Months</td></tr>
</table>

Sitagliptin Phosphate:
<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>1827-0001-19010</td><td>06 Months</td><td>36 Months</td></tr>
<tr><td>1827-0001-19011</td><td>06 Months</td><td>36 Months</td></tr>
<tr><td>1827-0001-19012</td><td>06 Months</td><td>36 Months</td></tr>
</table>
</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 mediums) 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>Pharmaceutical Equivalence have been established against STEGLUJAN™ 15/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use by Merck Sharp & Dohme Corp. by performing quality tests (Description, Identification, Dissolution and Assay).

CDP have been performed against the same brand i.e. STEGLUJAN™ 15/100mg (Ertugliflozin / Sitagliptin) tablets, for oral use in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 80% of both test and reference samples showed release within 15 minutes.</td></tr>
<tr><td></td><td>Analytical method validation / verification of product</td><td>Method validation studies have been submitted including Verification of Assay Method, Specificity, Accuracy, Precision, Linearity concentration and Peak Range.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td>Ertugliflozin L Pyroglutamic acid:
Zhejiang TOP Medicine Co. Ltd.</td></tr>
</table>

	Sitagliptin Phosphate Monohydrate: Zhejiang Yongtai Pharmaceutical Co. Ltd.		
API Lot No.	Ertugliflozin L Pyroglutamic acid: PF-20200601 Sitagliptin Phosphate Monohydrate: 1827-0001-21014		
Description of Pack (Container closure system)	Alu-Alu Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ESH-001	ESH-002	ESH-003
Batch Size	2,500 Tab	2,500 Tab	2,500 Tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	29-09-2021	29-09-2021	29-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	Firm has referred to onsite inspection report of their products EMPAZON 10mg Tablets / EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules / Dayzol 60mg Capsules (Dexlansoprazole) conducted on 1st June, 2021 and presented in 307th meeting of Registration Board held on 08-10th June , 2021.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Ertugliflozin L Pyroglutamic acid: Copy of GMP certificate issued by Zhejiang Medical Center for Economic Development, China along with copy of License. Sitagliptin Phosphate Monohydrate: Copy of GMP certificate issued by Zhejiang Food and Drug Administration, China along with copy of License.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Ertugliflozin L Pyroglutamic acid: Copy of Invoice No. CF20210706 dated 05/08/ 2021 duly attested by Assistant Director, DRAP, Lahore on 25-08-2021 has been provided. Sitagliptin Phosphate Monohydrate: Copy of Invoice No. 21APE040413 dated 08/05/ 2021 duly attested by Assistant Director, DRAP, Lahore on 21-05-2021 has been provided.
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:

Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated) and 09 Months (Real Time) vide Dy. No. 3654 dated 08 FEB 2023.

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.**

1003.	Name, address of Applicant / Marketing Authorization Holder	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2624 dated 27th January 2022.
	Details of fee submitted	PKR 30,000/- dated 20 December, 2021
	The proposed proprietary name / brand name	**Silo Capsules 4mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Silodosin…… 4mg (Innovator's Specifications)
	Pharmaceutical form of applied drug	White granular powder filled in Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	G04CA04 Drugs Used In Benign Prostatic Hypertrophy, Alpha-adrenoreceptor antagonists.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	10's, 20's & 30's capsules.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	RAPAFLO® (silodosin) capsules, for oral use by Watson Pharmaceuticals, Inc. (USFDA Approved).
	For generic drugs (me-too status)	Sildat Capsule 4mg (Reg. No. 105264) of M/s SAMI Pharmaceuticals Pvt. Ltd.
	GMP status of the Finished product manufacturer	GMP Certificate granted on 17th December, 2020 (based on evaluation conducted on 09-11-2020) issued for Tablet (General & Antibiotic), Capsule (Antibiotics, Non- Antibiotic and Cephalosporin), Oral Liquids (General) Dry powder Suspension (Cephalosporin) Injections (General) and Biotech (Prefilled Syringes, Ampoules, Vials) Sections.
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd. No. 15, Donghai 5th Avenue, Zhejiang Provincial

		Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Silodosin is present in Japanese Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	API 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: 20150328, 20150406 and 20150513.
	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 mediums) 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 SILDAT Capsule 4mg of SAMI Pharmaceuticals (Pvt.) Ltd. by performing quality tests (Description, Identification, Dissolution and Assay). CDP have been performed against the same brand i.e. SILDAT Capsule 4mg of SAMI Pharmaceuticals (Pvt.) Ltd. in Acid Medium 0.1N HCl (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). More than 85% of both test and reference samples showed release within 15 minutes.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Robustness, Accuracy, Precision (Repeatability) and Specificity.
STABILITY STUDY DATA		
Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd. China	
API Lot No.	13000-180801	

Description of Pack (Container closure system)	Alu-Alu blister with cold aluminum foil (10's, 20's & 30's).		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1,500 Capsules	1,500 Capsules	1,500 Capsules
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	14-01-2020	14-01-2020	14-01-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	The Firm have referred to their Product Sijlan 8mg Capsules (Silodosin 8mg) Reg. No. 114166 Registered on 06th December 2022. The Firm have also referred to onsite inspection report of their products DASCOT (Daclatasvir) 30mg & 60mg and VELSCOT (Sofosbuvir + Velpatasvir) 400mg/100mg approved in 278th Meeting of Registration Board held on 29-31st January 2018.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. 202004051 issued by Zhejiang Medical Products Service Center for Information Publicity and Development. Mentioned validity until Dec.22, 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Clearance Certificate from AD (I&E) Islamabad dated 17-01-2019 for Silodosin 90.45 Grams Batch 13000-180801 vide Invoice No. TY118872 dated 07-12-2018 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:

Decision: Approved.

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

Case No. 02: Priority applications on the basis of Export Facilitation of Locally Manufactured Drugs:

The following dossiers have been evaluated reference to the letter No. F.1-6/2019-PR-I (EFD) dated 06th October 2022 from Assistant Director (PR-I/EFD) wherein it has been stated that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical

i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm (M/s. Hilton Pharma (Pvt.) Ltd.) have achieved the benchmark of export of more than 100,000 USD (1123,074.35 USD) during the fiscal year 2021-2022 and have submitted their applications for priority consideration in lieu of export facilitation for Registration Board please: -

1004.	**Name and address of manufacturer / Applicant**	**M/s. Hilton Pharma (Pvt.) Ltd. Plot No. 13-14 & 43, Sector-15, Korangi, Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	**Ertu-Met Tablets 2.5mg / 500mg**
	Composition	Each Film-Coated Tablet Contains: Ertugliflozin L-Pyroglutamic acid equivalent to Ertugliflozin … 2.5mg Metformin HCl (USP)… 500mg (Innovator's Specifications)
	Diary No. Date of R& I & fee	Duplicate Dossier & Photocopy of Challan: Dy. No. 16318(R&I) dated 03-05-2018 Fee Rs: 50,000/- dated: 23.04.2018, vide deposit slip No. 0719470.
	Pharmacological Group	A10BD23 Drugs used in Diabetes, Combinations of oral blood glucose lowering drugs.
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	7's, 10's, 14's, 28's & 30's ; As per DPC.
	Approval status of product in Reference Regulator Authorities	SEGLUROMET™ (Ertugliflozin and Metformin hydrochloride) tablets, for oral use by M/s Merck Sharp & Dohme Corp., (USFDA Approved).
	Me-too status	Gujamet 2.5/500mg Tablet (Reg. No. 112083) of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	GMP status	GMP Certificate No. 03/2023-DRAP (K) dated 24th January, 2023 issued based on evaluation conducted on 23rd January, 2023.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Manufacturer of API	Ertugliflozin L-Pyroglutamic acid: M/s. Chifeng Arker Pharmaceutical Technology Co., Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. Metformin HCl: M/s. Abhilash chemicals and pharmaceuticals Pvt. Ltd. 26/D, Ganeshapuram. K. Pudur. Madurai 625 007. Tamilnadu, India.		
API Lot No.	Ertugliflozin L-Pyroglutamic acid: Batch No. D84-201101 Metformin HCl: Batch No. MET/B/01/20100269.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ERM-032-02/21	ERM-033-03/21	ERM-004-01/21
Batch Size	1,500 Tablets	1,500 Tablets	1,500 Tablets
Manufacturing Date	01.2021	01.2021	01.2021

Date of Initiation	19.02.2021	19.02.2021	19.02.2021
No. of Batches	03		
Date of Submission	03.05.2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
43.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following observations were reported in the report: i. The HPLC software is 21 CFR compliant. ii. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
44.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	1. Copies of COAs (Batch # D84-201101) of API (Ertugliflozin) from M/s Chifeng Arker Pharmaceutical Technology Co., Ltd., China and M/s Hilton Pharma (Pvt.) Ltd are submitted. 2. Copies of COAs (Batch # MET/B/01/20100269) of API (Metformin hydrochloride) from M/s Abhilash chemicals and pharmaceuticals Pvt. Ltd. India and M/s Hilton Pharma (Pvt.) Ltd are submitted.
45.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted.
46.	Stability study data of API from API manufacturer	APIs' Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 Months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 Months Ertugliflozin L-Pyroglutamic acid: Batches: D84-161201, D84-161202, D84-170101 Metformin HCl: Batches: MET/1010525, MET/0910364, MET/08/00408, MET/07/00848, MET/06/00548, MET/06/00547
47.	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: Ertugliflozin L-Pyroglutamic acid:

<table>
<tr><td></td><td></td><td>GMP Certificate No. 20160053 & 91150400720172660N issued by China council for the promotion of international trade (CCPIT) valid till 28.12.2025.

Metformin HCl:
GMP certificate No. K Dis. No: 14957/D1/4/2021 issued by Department of food safety and drugs control administration government of Tamilnadu, India valid till 31.12.2024.</td></tr>
<tr><td>48.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>AD attested Invoice No. PSPW-201113 on 23-11-2020 for Ertugliflozin L-Pyroglutamic acid, Batch No. D84-201101

AD attested Invoice No. GSTE-099/2020-21 on 06-11-2020 for Metformin HCl, Batch No. MET/B/01/20100269.</td></tr>
<tr><td>49.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>50.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>51.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not applicable. The Firm have claimed the same qualitative formulation as Innovator (Stegluromet Tablets 2.5mg+500mg) is using.</td></tr>
<tr><td>52.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>ERM-032-02/21</td><td>1,500 Tablets</td><td>01.2021</td></tr>
<tr><td>ERM-033-03/21</td><td>1,500 Tablets</td><td>01.2021</td></tr>
<tr><td>ERM-004-01/21</td><td>1,500 Tablets</td><td>01.2021</td></tr>
</table></td></tr>
<tr><td>53.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed between Ertu-Met Tablets (2.5/500mg) Batch No. ERM-004-01/21 and Steglumet Tablets (2.5/500mg), Batch No. l017792 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8) and showed Comparable Dissolution Profile.</td></tr>
<tr><td>54.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>55.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>56.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator:
Furthermore, the applicant has also applied for Exemption from (PSI / Onsite verification) based on previous onsite inspection report and have submitted data regarding PSI exemption vide Dy. No. 32851 dated 02 DEC 2021.</td></tr>
<tr><td colspan="3">Decision: Approved with Innovator' 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.</td></tr>
</table>

- **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board**

1005.	Name and address of manufacturer / Applicant	M/s. Hilton Pharma (Pvt.) Ltd. Plot No. 13-14 & 43, Sector-15, Korangi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ertu-Met Tablets 2.5mg / 1000mg
	Composition	Each Film-Coated Tablet Contains: Ertugliflozin L-Pyroglutamic acid equivalent to Ertugliflozin … 2.5mg Metformin HCl (USP)… 1000mg (Innovator's Specifications)
	Diary No. Date of R& I & fee	Duplicate Dossier & Photocopy of Challan: Dy. No. 16319(R&I) dated 03-05-2018 Fee Rs: 50,000/- dated: 23.04.2018, vide deposit slip No. 0719471.
	Pharmacological Group	A10BD23 Drugs used in Diabetes, Combinations of oral blood glucose lowering drugs.
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	7's, 10's, 14's, 28's & 30's ; As per DPC.
	Approval status of product in Reference Regulator Authorities	SEGLUROMET™ (Ertugliflozin and Metformin hydrochloride) tablets, for oral use by M/s Merck Sharp & Dohme Corp., (USFDA Approved).
	Me-too status	Gujamet 2.5/1000mg Tablet (Reg. No. 112082) of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	GMP status	GMP Certificate No. 03/2023-DRAP (K) dated 24th January, 2023 issued based on evaluation conducted on 23rd January, 2023.
	Remarks of the Evaluator	As in stability evaluation.

STABILITY STUDY DATA

Manufacturer of API	Ertugliflozin L-Pyroglutamic acid: M/s. Chifeng Arker Pharmaceutical Technology Co., Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. Metformin HCl: M/s. Abhilash chemicals and pharmaceuticals Pvt. Ltd. 26/D, Ganeshapuram. K. Pudur. Madurai 625 007. Tamilnadu, India.		
API Lot No.	Ertugliflozin L-Pyroglutamic acid: Batch No. D84-201101 Metformin HCl: Batch No. MET/B/01/20100269.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ERM-074-08/21	ERM-075-09/21	ERM-076-10/21
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	17.03.2021	17.03.2021	17.03.2021

No. of Batches	03	
Date of Submission	03.05.2018	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following observations were reported in the report: iv. The HPLC software is 21 CFR compliant. v. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. vi. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	3. Copies of COAs (Batch # D84-201101) of API (Ertugliflozin) from M/s Chifeng Arker Pharmaceutical Technology Co., Ltd., China and M/s Hilton Pharma (Pvt.) Ltd are submitted. 4. Copies of COAs (Batch # MET/B/01/20100269) of API (Metformin hydrochloride) from M/s Abhilash chemicals and pharmaceuticals Pvt. Ltd. India and M/s Hilton Pharma (Pvt.) Ltd are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted.
4.	Stability study data of API from API manufacturer	APIs' Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 Months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 Months Ertugliflozin L-Pyroglutamic acid: Batches: D84-161201, D84-161202, D84-170101 Metformin HCl: Batches: MET/1010525, MET/0910364, MET/08/00408, MET/07/00848, MET/06/00548, MET/06/00547
5.	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: Ertugliflozin L-Pyroglutamic acid:

<table>
<tr><td></td><td></td><td>GMP Certificate No. 20160053 & 91150400720172660N issued by China council for the promotion of international trade (CCPIT) valid till 28.12.2025.

Metformin HCl:
GMP certificate No. K Dis. No: 14957/D1/4/2021 issued by Department of food safety and drugs control administration government of Tamilnadu, India valid till 31.12.2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>AD attested Invoice No. PSPW-201113 on 23-11-2020 for Ertugliflozin L-Pyroglutamic acid, Batch No. D84-201101

AD attested Invoice No. GSTE-099/2020-21 on 06-11-2020 for Metformin HCl, Batch No. MET/B/01/20100269.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not applicable. The Firm have claimed the same qualitative formulation as Innovator (Stegluromet Tablets 2.5mg+1000mg) is using.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>ERM-074-08/21</td><td>1,500 Tablets</td><td>02.2021</td></tr>
<tr><td>ERM-076-10/21</td><td>1,500 Tablets</td><td>02.2021</td></tr>
<tr><td>ERM-075-09/21</td><td>1,500 Tablets</td><td>02.2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed between Ertu-Met Tablets (2.5/1000mg) Batch No. ERM-074-08/21 and Stegluromet Tablets (2.5/1000mg), Batch No. T014796 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8) and showed Comparable Dissolution Profile.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator:

Furthermore, the applicant has also applied for Exemption from (PSI / Onsite verification) based on previous onsite inspection report and have submitted data regarding PSI exemption vide Dy. No. 32851 dated 02 DEC 2021.</td></tr>
<tr><td colspan="3">Decision: Approved with Innovator' 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.</td></tr>
</table>

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board**

1006.	Name and address of manufacturer / Applicant	M/s. Hilton Pharma (Pvt.) Ltd. Plot No. 13-14 & 43, Sector-15, Korangi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	**Ertu-Met Tablets 7.5mg/ 500mg**
	Composition	Each Film-Coated Tablet Contains: Ertugliflozin L-Pyroglutamic acid equivalent to Ertugliflozin … 7.5mg Metformin HCl (USP)… 500mg (Innovator's Specifications)
	Diary No. Date of R& I & fee	Duplicate Dossier & Photocopy of Challan: Dy. No. 16320(R&I) dated 03-05-2018 Fee Rs: 50,000/- dated: 23.04.2018, vide deposit slip No. 0719474.
	Pharmacological Group	A10BD23 Drugs used in Diabetes, Combinations of oral blood glucose lowering drugs.
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	7's, 10's, 14's, 28's & 30's ; As per DPC.
	Approval status of product in Reference Regulator Authorities	SEGLUROMET™ (Ertugliflozin and Metformin hydrochloride) tablets, for oral use by M/s Merck Sharp & Dohme Corp., (USFDA Approved).
	Me-too status	Gujamet 7.5/500mg Tablet (Reg. No. 112081) of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	GMP status	GMP Certificate No. 03/2023-DRAP (K) dated 24th January, 2023 issued based on evaluation conducted on 23rd January, 2023.
	Remarks of the Evaluator	As in stability evaluation.

STABILITY STUDY DATA

Manufacturer of API	Ertugliflozin L-Pyroglutamic acid: M/s. Chifeng Arker Pharmaceutical Technology Co., Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. Metformin HCl: M/s. Abhilash chemicals and pharmaceuticals Pvt. Ltd. 26/D, Ganeshapuram. K. Pudur. Madurai 625 007. Tamilnadu, India.		
API Lot No.	Ertugliflozin L-Pyroglutamic acid: Batch No. D84-201101 Metformin HCl: Batch No. MET/B/01/20100269.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ERM-070-07/21	ERM-071-08/21	ERM-072-09/21
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets

Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	25.03.2021	25.03.2021	25.03.2021
No. of Batches	03		
Date of Submission	03.05.2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following observations were reported in the report: vii. The HPLC software is 21 CFR compliant. viii. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. ix. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	5. Copies of COAs (Batch # D84-201101) of API (Ertugliflozin) from M/s Chifeng Arker Pharmaceutical Technology Co., Ltd., China and M/s Hilton Pharma (Pvt.) Ltd are submitted. 6. Copies of COAs (Batch # MET/B/01/20100269) of API (Metformin hydrochloride) from M/s Abhilash chemicals and pharmaceuticals Pvt. Ltd. India and M/s Hilton Pharma (Pvt.) Ltd are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted.
4.	Stability study data of API from API manufacturer	APIs' Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 Months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 Months Ertugliflozin L-Pyroglutamic acid: Batches: D84-161201, D84-161202, D84-170101 Metformin HCl: Batches: MET/1010525, MET/0910364, MET/08/00408, MET/07/00848, MET/06/00548, MET/06/00547

<table>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate:

Ertugliflozin L-Pyroglutamic acid:
GMP Certificate No. 20160053 & 91150400720172660N issued by China council for the promotion of international trade (CCPIT) valid till 28.12.2025.

Metformin HCl:
GMP certificate No. K Dis. No: 14957/D1/4/2021 issued by Department of food safety and drugs control administration government of Tamilnadu, India valid till 31.12.2024.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>AD attested Invoice No. PSPW-201113 on 23-11-2020 for Ertugliflozin L-Pyroglutamic acid, Batch No. D84-201101

AD attested Invoice No. GSTE-099/2020-21 on 06-11-2020 for Metformin HCl, Batch No. MET/B/01/20100269.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not applicable. The Firm have claimed the same qualitative formulation as Innovator (Segluromet Tablets 7.5mg+500mg) is using.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>ERM-070-07/21</td><td>1500 Tablets</td><td>02.2021</td></tr>
<tr><td>ERM-071-08/21</td><td>1500 Tablets</td><td>02.2021</td></tr>
<tr><td>ERM-072-09/21</td><td>1500 Tablets</td><td>02.2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed between Ertu-Met Tablets (7.5/500mg) Batch No. ERM-058-06/21 and Segluromet Tablets (7.5/500mg), Batch No. G013693 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8) and showed Comparable Dissolution Profile.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator
Furthermore, the applicant has also applied for Exemption from (PSI / Onsite verification) based on previous onsite inspection report and have submitted data regarding PSI exemption vide Dy. No. 32851 dated 02 DEC 2021.</td></tr>
<tr><td colspan="3">Decision: Approved with Innovator’ 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.</td></tr>
</table>

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board**

1007.	Name and address of manufacturer / Applicant	M/s. Hilton Pharma (Pvt.) Ltd. Plot No. 13-14 & 43, Sector-15, Korangi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ertu-Met Tablets 7.5mg/ 1000mg
	Composition	Each Film-Coated Tablet Contains: Ertugliflozin L-Pyroglutamic acid equivalent to Ertugliflozin … 7.5mg Metformin HCl (USP)… 1000mg (Innovator's Specifications)
	Diary No. Date of R& I & fee	Duplicate Dossier & Photocopy of Challan: Dy. No. 16321(R&I) dated 03-05-2018 Fee Rs: 50,000/- dated: 23.04.2018, vide deposit slip No. 0719473.
	Pharmacological Group	A10BD23 Drugs used in Diabetes, Combinations of oral blood glucose lowering drugs.
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	7's, 10's, 14's, 28's & 30's ; As per DPC.
	Approval status of product in Reference Regulator Authorities	SEGLUROMET™ (Ertugliflozin and Metformin hydrochloride) tablets, for oral use by M/s Merck Sharp & Dohme Corp., (USFDA Approved).
	Me-too status	Gujamet 7.5/1000mg Tablet (Reg. No. 112080) of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	GMP status	GMP Certificate No. 03/2023-DRAP (K) dated 24th January, 2023 issued based on evaluation conducted on 23rd January, 2023.
	Remarks of the Evaluator	As in stability evaluation.

STABILITY STUDY DATA

Manufacturer of API	Ertugliflozin L-Pyroglutamic acid: M/s. Chifeng Arker Pharmaceutical Technology Co., Ltd. No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. Metformin HCl: M/s. Abhilash chemicals and pharmaceuticals Pvt. Ltd. 26/D, Ganeshapuram. K. Pudur. Madurai 625 007. Tamilnadu, India.		
API Lot No.	Ertugliflozin L-Pyroglutamic acid: Batch No. D84-201101 Metformin HCl: Batch No. MET/B/01/20100269.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ERM-047-05/21	ERM-048-06/21	ERM-049-07/21
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets

Manufacturing Date	02.2021	02.2021	02.2021
Date of Initiation	24.02.2021	24.02.2021	24.02.2021
No. of Batches	03		
Date of Submission	03.05.2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "HILVEL 400mg + 100mg (Sofosbuvir +Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following observations were reported in the report: x. The HPLC software is 21 CFR compliant. xi. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available. xii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	7. Copies of COAs (Batch # D84-201101) of API (Ertugliflozin) from M/s Chifeng Arker Pharmaceutical Technology Co., Ltd., China and M/s Hilton Pharma (Pvt.) Ltd are submitted. 8. Copies of COAs (Batch # MET/B/01/20100269) of API (Metformin hydrochloride) from M/s Abhilash chemicals and pharmaceuticals Pvt. Ltd. India and M/s Hilton Pharma (Pvt.) Ltd are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Submitted.
4.	Stability study data of API from API manufacturer	APIs' Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 Months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 Months Ertugliflozin L-Pyroglutamic acid: Batches: D84-161201, D84-161202, D84-170101 Metformin HCl: Batches: MET/1010525, MET/0910364, MET/08/00408, MET/07/00848, MET/06/00548, MET/06/00547

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GMP Certificate No. 20160053 & 91150400720172660N issued by China council for the promotion of international trade (CCPIT) valid till 28.12.2025.

Metformin HCl:
GMP certificate No. K Dis. No: 14957/D1/4/2021 issued by Department of food safety and drugs control administration government of Tamilnadu, India valid till 31.12.2024.</td></tr>
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AD attested Invoice No. GSTE-099/2020-21 on 06-11-2020 for Metformin HCl, Batch No. MET/B/01/20100269.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
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<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Not applicable. The Firm have claimed the same qualitative formulation as Innovator (Segluromet Tablets 7.5mg+1000mg) is using.</td></tr>
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<tr><td>ERM-048-06/21</td><td>1500 Tablets</td><td>02.2021</td></tr>
<tr><td>ERM-049-07/21</td><td>1500 Tablets</td><td>02.2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Comparative dissolution was performed between Ertu-Met Tablets (7.5/1000mg) Batch No. ERM-049-07/21 and Segluromet Tablets (7.5/1000mg), Batch No. K016734 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8) and showed Comparable Dissolution Profile.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator

Furthermore, the applicant has also applied for Exemption from (PSI / Onsite verification) based on previous onsite inspection report and have submitted data regarding PSI exemption vide Dy. No. 32851 dated 02 DEC 2021.</td></tr>
<tr><td colspan="3">Decision: Approved with Innovator’ 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.</td></tr>
</table>

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board**

Case No. 03: Withdrawal of CTD (Form 5F) Application Dossiers:

M/s Hilton Pharma Pvt Ltd. Karachi vide their letter Ref. No. MN/ZA/230227-01 dated 27th Feb. 2023 have submitted that they had applied the following Product Registration Applications on both Form 5D and Form 5F, and have requested to consider Form 5D application dossiers and to withdraw following CTD / Form 5F applications: -

Sr. No.	Name and Address of Manufacturer	Brand Name	Composition	Type of Form, Diary No and Date of Submission, Deposited Fee and Date	Date
1008.	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan	Ertihil-Met 2.5/500 mg Tablet	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertgliflozin…2.5mg Metformin Hcl…500mg	Form-5F Dy.No 11029 dated 06-05-2022 Rs.30,000/- dated 18-03-2022	2022-05-06
1009.	-do-	Ertihil-Met 2.5/1000 mg Tablet	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertgliflozin…2.5mg Metformin Hcl…1000mg	Form-5F Dy.No 11033 dated 06-05-2022 Rs.30,000/- dated 18-03-2022	2022-05-06
1010.	-do-	Ertihil-Met 7.5/500 mg Tablet	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertgliflozin…7.5mg Metformin Hcl…500mg	Form-5F Dy.No 11030 dated 06-05-2022 Rs.30,000/- dated 18-03-2022	2022-05-06
1011.	-do-	Ertihil-Met 7.5/1000 mg Tablet	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertgliflozin…7.5mg Metformin Hcl…1000mg	Form-5F Dy.No 11031 dated 06-05-2022 Rs.30,000/- dated 18-03-2022	2022-05-06

Decision: Registration Board acceded to the request of withdrawal of above cited applications of Form 5F from firm and declared them as disposed of.

Agenda of Evaluator PEC-XXII

Case No. 01 – Routine registration application of Human drugs on Form-5 (Local)

1012.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Xenova-CF 12.5mg Tablet
	Composition	Each enteric film coated controlled release tablet contains Paroxetine (as paroxetine hydrochloride hemihydrate)….12.5mg
	Diary No. Date of R & I & fee	Dy. No. 17321 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768896 dated 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors

		ATC code: N06AB05
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Paxil CR Tablet approved by US-FDA
	Me-too status	Panox CR 12.5mg tablet Reg. No. 081953 by M/s. Regal Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1013.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Xenova 20mg tablet
	Composition	Each film coated tablet contains Paroxetine (as paroxetine hydrochloride hemihydrate)….20mg
	Diary No. Date of R & I & fee	Dy. No. 17329 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768895 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC code: N06AB05
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Paroxetine 20 mg film-coated tablets approved by MHRA
	Me-too status	Parotine 20mg tablet Reg. No. 61924 by M/s. Mediate Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1014.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Xenova-CF 25mg tablet
	Composition	Each enteric film coated controlled release tablet contains Paroxetine (as paroxetine hydrochloride hemihydrate)….25mg
	Diary No. Date of R & I & fee	Dy. No. 17327 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768897 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC code: N06AB05
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Paxil CR Tablet approved by US-FDA
	Me-too status	Panox CR tablet Reg. No. 081954 by M/s. Regal Pharma
	GMP status	Not Provided

	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1015.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novadone 1mg tablet
	Composition	Each Film Coated tablet contains: Risperidone…1mg
	Diary No. Date of R & I & fee	Dy. No. 17323 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0791480 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antipsychotics ATC code: N05AX08
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Risperidone 1mg Film coated tablets approved by MHRA
	Me-too status	Riss 1mg film coated tablets Reg. No. 080379 by M/s. Shawan Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1016.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novadone 2mg tablet
	Composition	Each Film Coated Tablet contains: Risperidone…2mg
	Diary No. Date of R & I & fee	Dy. No. 17333 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0791481 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antipsychotics ATC code: N05AX08
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Risperidone 2mg Film coated tablets approved by MHRA
	Me-too status	Riss 2mg film coated tablets Reg. No. 080378 by M/s. Shawan Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1017.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.

	Brand Name + Dosage Form + Strength	Novasimet 50/500 tablets
	Composition	Each Film coated tablet contains: Sitagliptin (as Sitagliptin Phosphate Monohydrate)…50mg & Metformin HCl…500mg
	Diary No. Date of R & I & fee	Dy. No. 17322 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0791477 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC code: A10BD07
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Janumet Tablet approved by TGA
	Me-too status	Neoglip 50/500 Tablets Reg. No. 53099 by M/s. Atco
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required. iv. Firm has applied for Manufacturers specifications and monograph of applied product is not available in any Pharmacopoeia.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1018.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novasimet 50/1000 tablets
	Composition	Each Film coated tablet contains: Sitagliptin (as Sitagliptin Phosphate Monohydrate)…50mg & Metformin HCl…1000mg
	Diary No. Date of R & I & fee	Dy. No. 17334 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0798900 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC code: A10BD07
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Janumet Tablet approved by TGA
	Me-too status	Neoglip 50/1000mg tablet Reg. No. 53100 by M/s. Atco
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required. iv. Firm has applied for Manufacturers specifications and monograph of applied product is not available in any Pharmacopoeia.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1019.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novazole 20mg Tablet
	Composition	Each Delayed Release tablet contains:

		Rabeprazole Sodium…20mg
	Diary No. Date of R & I & fee	Dy. No. 17332 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0791478 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Proton pump inhibitors ATC code: A02BC04
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ACIPHEX tablet manufactured by M/s. Woodward approved by US-FDA
	Me-too status	Rabecid tablet Reg. No. 28360 Mfg. by M/s. Highnoon
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required. iv. Firm has applied for Manufacturers specifications and monograph of applied product is not available in any Pharmacopoeia.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1020.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novazole 10mg Tablet
	Composition	Each Delayed Release Tablet contains: Rabeprazole Sodium…10mg
	Diary No. Date of R & I & fee	Dy. No. 17328 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0791479 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Proton pump inhibitors ATC code: A02BC04
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Rabeprazole Sodium tablet manufactured by M/s. Dr. Reddy approved by US-FDA
	Me-too status	Rabecid tablet Reg. No. 28361 Mfg. by M/s. Highnoon
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required. iv. Firm has applied for Manufacturers specifications and monograph of applied product is not available in any Pharmacopoeia.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1021.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novobast 10mg Tablets
	Composition	Each Film coated tablet contains: Ebastine…10mg
	Diary No. Date of R & I & fee	Dy. No. 17330 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768891 dated 06-03-2019, 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	As per SRO.
	Approval status of product in Reference Regulatory Authorities	EBASTINE ARROW 10 mg film-coated tablet manufactured by ARROW GENERICS approved by ANSM France
	Me-too status	Histalis 10mg tablet Reg. No. 96727 Mfg. by M/s. Titlis Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1022.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novobast 20mg Tablets
	Composition	Each Film coated tablet contains: Ebastine…20mg
	Diary No. Date of R & I & fee	Dy. No. 17324 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768890 dated 06-03-2019, 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	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALASTIN 20mg Film coated tablet Mfg. by UXA FARMA, S.A approved by CIMA, Spain.
	Me-too status	Kaxtib 20mg tablet Reg. No. 96355 Mfg. by M/s. Semos Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1023.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novapanto 40mg Tablets
	Composition	Each Delayed Release Tablet Contains: Pantoprazole (as Sodium Sesquihydrate)…40mg
	Diary No. Date of R & I & fee	Dy. No. 17331 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768894 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC02
	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	Protonix 40mg Delayed Release tablet approved by US-FDA
	Me-too status	Rubal 40mg tablet Reg. No. 95820 Mfg. by M/s. Demont Research Laboratories

	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1024.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novamate 50mg tablet
	Composition	Each Film Coated Tablet: Topiramate…50mg
	Diary No. Date of R & I & fee	Dy. No. 17325 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768899 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX11
	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	Topiramate 50mg film coated tablets approved by MHRA
	Me-too status	Topival 50mg Tablet Reg. No. 92354 Mfg. by Seraph Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1025.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novomont 10mg Tablet
	Composition	Each Film coated tablet contains: Montelukast (As Montelukast Sodium)…10mg
	Diary No. Date of R & I & fee	Dy. No. 17320 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768893 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Leukotriene receptor antagonists ATC Code: R03DC03
	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	Montelukast 10mg Film coated tablets approved by MHRA.
	Me-too status	Koster 10mg Tablet Reg. No. 95331 Mfg. by M/s. Regal Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	

1026.	Name and address of manufacturer/ Applicant	M/s. Novartana Pharmaceuticals (Pvt.) Ltd., 87-B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	Novafine 125mg Tablet
	Composition	Each tablet contains: Terbinafine (as Terbinafine HCl)…125mg
	Diary No. Date of R & I & fee	Dy. No. 17326 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0768898 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Antifungals for systemic use ATC Code: D01BA02
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Terbinafine 125mg tablets approved by MHRA
	Me-too status	Tinadew 125mg Tablet Reg. No. 95510 Mfg. by Dew-Max Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Valid copy of DML is required ii. Latest GMP certificate/inspection report of M/s Novartana Pharmaceuticals conducted within last 03 years is required. iii. Section Approval Letter of Novartana Pharmaceuticals is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1027.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Unizapine 15mg Tablet
	Composition	Each Tablet Contains: Mirtazapine…15mg
	Diary No. Date of R & I & fee	Dy. No. 17211 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796942 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antidepressants ATC code: N06AX11
	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	Mirtazapine 15mg tablets approved by MHRA
	Me-too status	Mirzace 15mg Tablet Reg. No. 108256 Mfg. by M/s. FYNK Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. The product approved in RRA is film coated whereas applied formulation is uncoated. Correction along with applicable fee is required. iv. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP).
	Decision: Approved with USP specifications as per following label claim: **Each film coated Tablet Contains:** **Mirtazapine…15mg**	

	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.	
1028.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Acetech 200mg Tablets
	Composition	Each Tablet contains: Aceclofenac…200mg
	Diary No. Date of R & I & fee	Dy. No. 17221 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0835127 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Acetic acid derivatives and related substances ATC code: M01AB16
	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	Could not be confirmed / Not available.
	Me-too status	Could not be confirmed / Not available.
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. iv. Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1029.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Unitram 50mg capsule
	Composition	Each capsule contains: Tramadol…50mg
	Diary No. Date of R & I & fee	Dy. No. 17216 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796856 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other opioids ATC code: N02AX02
	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	Tramadol HCl 50mg Capsules approved by MHRA
	Me-too status	Tramaway 50mg Capsules Reg. No. 75328 Mfg. by M/s. Caraway Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required.

		ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (BP).
	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.	
1030.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Lumisuag 80/480mg tablet
	Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
	Diary No. Date of R & I & fee	Dy. No. 17248 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0835104 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Artemisinin and derivatives, combinations ATC code: P01BF01
	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	WHO prequalified formulation (Reference Number: MA108)
	Me-too status	Temprin Plus Tablets Reg. No. 75357 Mfg. by M/s. Shaigan Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Finished Product Specifications applied are Innovator's specifications however the finished product specifications are present in International Pharmacopeia. Finished product specifications shall be revised to IP specifications with submission of applicable fee. iv. Reference product is available as coated tablet, whereas firm has applied for uncoated tablets, hence submit revised label claim.
	Decision: Approved as per IP specifications with following label claim: **Each film coated tablet contains:** **Artemether…80mg** **Lumefantrine…480mg** **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.**	
1031.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Dolotech 20mg Capsule
	Composition	Each Capsule contains: Duloxetine…20mg
	Diary No. Date of R & I & fee	Dy. No. 17238 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796947 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antidepressants ATC code: N06AX21
	Type of Form	Form-5
	Finished product Specification	

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cymbalta capsule Mfg. by Lilly approved by US-FDA
	Me-too status	
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Applicant has claimed the source of Duloxetine pallets as M/s. Vision Pharmaceuticals however the firm has not provided latest GMP of M/s. Vision Pharmaceuticals, Certificate of analysis of Duloxetine pallets and stability data of Duloxetine pallets.
	Decision: Approved with USP specifications as per following label claim: **Each Capsule contains:** **Duloxetine hydrochloride 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.**	
1032.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Respiritech 1mg tablet**
	Composition	Each tablet contains: Risperidone…1mg
	Diary No. Date of R & I & fee	Dy. No. 17239 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796852 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antipsychotics ATC code: N05AX08
	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	Risperidone 1mg Film coated tablets approved by MHRA
	Me-too status	Riss 1mg film coated tablets Reg. No. 080379 by M/s. Shawan Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP). iv. Reference product is available as Film coated tablet, whereas firm has applied for uncoated tablets, hence submit revised label claim.
	Decision: Approved with USP specifications as per following label claim: **Each film coated tablet contains:** **Risperidone ……. 1mg** **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.**	
1033.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Respiritech 2mg tablet

	Composition	Each tablet contains: Risperidone…2mg
	Diary No. Date of R & I & fee	Dy. No. 17217 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796853 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antipsychotics ATC code: N05AX08
	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	Risperidone 2mg Film coated tablets approved by MHRA
	Me-too status	Riss 2mg film coated tablets Reg. No. 080378 by M/s. Shawan Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP). iv. Reference product is available as Film coated tablet, whereas firm has applied for uncoated tablets, hence submit revised label claim.
	Decision: Approved with USP specifications as per following label claim: **Each film coated tablet contains:** **Risperidone ……. 1mg** **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.**	
1034.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Uniyetine CR 12.5mg tablet
	Composition	Each tablet contains: Paroxetine…12.5mg
	Diary No. Date of R & I & fee	Dy. No. 17217 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796853 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC code: N06AB05
	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	Paxil CR Tablet approved by US-FDA
	Me-too status	Panox CR 12.5mg tablet Reg. No. 081953 by M/s. Regal Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP). iv. Reference product is available as enteric film coated controlled release tablets containing Paroxetine as paroxetine hydrochloride hemihydrate, whereas firm

		has applied for uncoated tablets and has provided no details regarding the salt form to be used in the manufacturing process, hence submit revised label claim.
	Decision: Approved with USP specifications as per 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.**	
1035.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Uniyetine 20mg tablet
	Composition	Each tablet contains: Paroxetine…20mg
	Diary No. Date of R & I & fee	Dy. No. 17220 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796949 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC code: N06AB05
	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	Paroxetine 20 mg film-coated tablets approved by MHRA
	Me-too status	Parotine 20mg tablet Reg. No. 61924 by M/s. Mediate Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP). iv. Reference product is available as film coated tablets containing Paroxetine as paroxetine hydrochloride hemihydrate, whereas firm has applied for uncoated tablets and has provided no details regarding the salt form to be used in the manufacturing process, hence submit revised label claim.
	Decision: Approved with USP specifications as per following label claim: **Each Film Coated Tablet Contains:** **Paroxetine as HCl……..…25mg** **The firm shall submit fee of Rs.7,500/- for correction/pre-approval change in product label claim to film coatesd tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1036.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Unimate 50mg tablet
	Composition	Each tablet contains: Topiramate…50mg
	Diary No. Date of R & I & fee	Dy. No. 17218 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796940 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC code: N03AX11
	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	Topiarmate 50mg Film coated tablets approved by MHRA.
	Me-too status	Epirid 50mg Tablets Reg. No. 83511 Mfg. by M/s. Prays Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP). iv. Reference product is available as film coated tablets, whereas firm has applied for uncoated tablets, hence label claim needs to be revised.
	Decision: Approved with USP specifications as per following label claim: **Each Film Coated Tablet Contains:** **Topiramate…50mg** **The firm shall submit fee of Rs.7,500/- for correction/pre-approval change in product label claim to film coatesd tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1037.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Unimate 100mg tablet
	Composition	Each tablet contains: Topiramate…100mg
	Diary No. Date of R & I & fee	Dy. No. 17222 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796938 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC code: N03AX11
	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	Topiarmate 100mg Film coated tablets approved by MHRA.
	Me-too status	Tipra 100mg tablets Reg. No. 94044 Mfg. by M/s. Metro Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP). iv. Reference product is available as film coated tablets, whereas firm has applied for uncoated tablets, hence label claim needs to be revised.
	Decision: Approved with USP specifications as per following label claim: **Each Film Coated Tablet Contains:** **Topiramate…100mg** **The firm shall submit fee of Rs.7,500/- for correction/pre-approval change in product label claim to film coatesd tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1038.	Name and address of manufacturer/ Applicant	M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd, Plot No. 4/116, Sector 21, Korangi industrial Area, Karachi.

	Brand Name + Dosage Form + Strength	Unimotrigine 100mg tablet
	Composition	Each tablet contains: Lamotrigine…100mg
	Diary No. Date of R & I & fee	Dy. No. 17240 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0796925 dated 04-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC code: N03AX09
	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	Lamictal 100mg tablets mfg. by GSK approved by MHRA.
	Me-too status	Sportin 100mg Tablets Reg. No. 70346 Mfg. by M/s. Fassgen Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Uni-Tiech Pharmaceuticals conducted within last 03 years is required. ii. Section Approval Letter of M/s. Uni-Tiech Pharmaceuticals is required. iii. Reference of Finished Product Specifications is not provided. The monograph of applied product is available in Pharmacopeia (USP).
	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.**	
1039.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Fitbone 70mg tablet
	Composition	Each tablet contains: Alendronate Sodium Trihydrate Eq. to Alendronic Acid…70mg
	Diary No. Date of R & I & fee	Dy. No. 17439 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901404 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Drugs Affecting Bone Structure and Mineralization ATC Code: M05BA04
	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	Dronal Once Weekly 70mg tablet Mfg. by Merck Sharp & Dohme Limited, Approved by MHRA
	Me-too status	Deonate Tablets 70mg Reg. No. 68396 Mfg. by M/s. ICI Pakistan
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1040.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Spasnem 40mg tablet
	Composition	Each tablet contains: Otilonium Bromide…40mg

	Diary No. Date of R & I & fee	Dy. No. 17437 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815591 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Synthetic anticholinergics, quaternary ammonium compounds ATC code: A03AB06
	Type of Form	Form-5
	Finished product Specification	Rotex Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Otilonio Stada 40 mg by Laboratorio Stada, Sl Approved by CIMA Spain.
	Me-too status	Otomin Tablet Reg. No. 059407 Mfg. by Genome Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications. iii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1041.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Tezmin 2mg tablet
	Composition	Each tablet contains: Terazosin Hydrochloride dehydrate Eq. to Terazosin…2mg
	Diary No. Date of R & I & fee	Dy. No. 17449 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815559 dated 06-03-2019, endorsed on 06.03.2019.
	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 2mg tablets approved by MHRA
	Me-too status	Tezim Tablet 5mg Reg. No. 64398 Mfg. by M/s. Genome Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1042.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Mezol 100mg tablet
	Composition	Each tablet contains: Mebendazole…100mg
	Diary No. Date of R & I & fee	Dy. No. 17420 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901402 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Vermox 100mg tablets approved by MHRA

	Me-too status	Meberown tablet Reg. No. 56379 Mfg. by M.s, Crown Pahrmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1043.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Azofan 50mg tablet
	Composition	Each tablet contains: Azathioprine…50mg
	Diary No. Date of R & I & fee	Dy. No. 17446 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815569 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other immunosuppressants ATC Code: L04AX01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Azathioprine 50mg Film coated tablets approved by MHRA
	Me-too status	Imuprine Tablet 50mg Reg. No. 107461 Mfg. By M/s. Hiranis Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1044.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Zynex 300mg Tablet
	Composition	Each tablet contains: Allopurinol…300mg
	Diary No. Date of R & I & fee	Dy. No. 17425 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815567 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Allopurinol 300mg tablets approved by MHRA
	Me-too status	Parinol 300mg Tablet Reg. No. 102404 Mfg. by M/s. Pulse Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1045.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Wormzol 200mg tablet

	Composition	Each Film coated tablet contains: Albendazole…200mg
	Diary No. Date of R & I & fee	Dy. No. 17456 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815558 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Benzimidazole derivatives ATC Code: P02CA03
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Albendazole 200mg tablets approved by US-FDA
	Me-too status	Larex Tablet Reg. No. 14290 Mfg. by M/s. Standpharm
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1046.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Novimax 10mg/10mg tablet
	Composition	Each tablet contains: Doxylamine succinate…10mg Pyridoxine Hydrochloride…10mg
	Diary No. Date of R & I & fee	Dy. No. 14062 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0610396 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Aminoalkyl ethers ATC Code: R06AA59
	Type of Form	Form-5
	Finished product Specification	Rotex Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	BONJESTA (doxylamine succinate and pyridoxine hydrochloride), extended-release tablets approved by US-FDA
	Me-too status	Vomenax Tablet Reg. No. 90791 Mfg. by M/s. SJ&G Fazul ellahi
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Clarification required for inactive used for the delayed release of the applied formulation. As submitted master formulation does not depicts any inactive for the delayed release effect of applied formulation. iii. Firm has claimed in-house specifications. iv. Revised label claim as Extended release tablet as per reference product with submission of applicable fee is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1047.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Aurora 500mg Dispersible Tablet
	Composition	Each Dispersible tablet contains: Deferasirox…500mg
	Diary No. Date of R & I & fee	Dy. No. 17450 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815566 dated 06-03-2019, endorsed on 06.03.2019.

	Pharmacological Group	Iron chelating agents ATC Code: V03AC03
	Type of Form	Form-5
	Finished product Specification	Rotex specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Deferasirox Alkem 500mg Dispersible Tablets approved by MHRA
	Me-too status	Dasirox 500 mg tablet Reg. No. 93971 Mfg. by M/s. CCL Pharmaceuticals.
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1048.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Trylin 35mg tablet
	Composition	Each tablet contains: Amitriptyline HCl…25mg
	Diary No. Date of R & I & fee	Dy. No. 17418 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815553 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Non-selective monoamine reuptake inhibitors ATC Code: N06AA09
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Amitriptyline 25mg tablets approved by MHRA
	Me-too status	Amitin tablet Reg. No. 38547 Mfg. by M/s. Glitz Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1049.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Exor-H 5/160/25mg tablet
	Composition	Each tablet contains: Amlodipine Besylate Eq. to Amlodipine…5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R & I & fee	Dy. No. 14200 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901418 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	EXFORGE HCT tablets approved by US-FDA
	Me-too status	Sofvasc Hct Tablets 5/160/25mg Reg. No. 77754 Mfg. by M/s. Wilsons Pharmaceuticals
	GMP status	Not Provided

	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1050.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Rancol XR 500mg tablet
	Composition	Each tablet contains: Ranolazine…500mg
	Diary No. Date of R & I & fee	Dy. No. 17424 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815596 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other cardiac preparations ATC Code: C01EB18
	Type of Form	Form-5
	Finished product Specification	Rotex Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ranexa 500 mg prolonged-release tablets approved by MHRA
	Me-too status	Razin ER Tablet 500mg Reg. No. 61103 Mfg. by M/s. Getz Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications. iii. Reference product is available as Prolonged-release tablets. Clarification required for inactive used for the prolonged-release of the applied formulation. As submitted master formulation does not depict any inactive for the prolonged release effect of applied formulation. iv. Revised label claim as Prolonged-release tablet as per reference product with submission of applicable fee is required
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1051.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Ferolic Tablet
	Composition	Each Tablet contains: Ferrous Fumarate…150mg Folic Acid…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 17442 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815563 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Iron in combination with folic acid ATC Code: B03AD02
	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	Folfe Tablets Reg. No. 41769 Mfg. by M/s. Wilshire Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.

		ii. 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 the updated status of GMP of the firm from the QA&LT divison.	
1052.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Cardem 2mg Tablet
	Composition	Each Tablet contains: Doxazosin (As Mesylate)…2mg
	Diary No. Date of R & I & fee	Dy. No. 17460 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815560 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC Code: C02CA04
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Doxazosin 2mg tablet approved by MHRA
	Me-too status	Uri-Dox 2mg Tab Reg. No. 73180 Mfg. by M/s. Valor Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1053.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Urazol 50mg tablet
	Composition	Each tablet contains: Propylthiouracil…50mg
	Diary No. Date of R & I & fee	Dy. No. 17453 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815556 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Thiouracils ATC Code: H03BA02
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Propylthiouracil tablets approved by MHRA
	Me-too status	Procarbizole tablet Reg. No. 40561 Mfg. by M/s. Pharmedic Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1054.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lorem 10mg tablet
	Composition	Each Tablet contains: Loratadine…10mg
	Diary No. Date of R & I & fee	Dy. No. 17431 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815597 dated 06-03-2019, endorsed on 06.03.2019.

	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Loratadine 10mg tablets approved by MHRA
	Me-too status	Andin Tablets 10mg Reg. No. 100088 Mfg. by M/s. Reign Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1055.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Oxiban 5mg tablet
	Composition	Each tablet contains: Oxybutynin Hydrochloride…5mg
	Diary No. Date of R & I & fee	Dy. No. 17441 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815555 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Drugs for urinary frequency and incontinence ATC Code: G04BD04
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Oxybutynin Hydrochloride Tablets 5mg approved by MHRA
	Me-too status	Taivor tablet Reg. No. 38385Mfg. by M/s. Razzee Therapeutics
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1056.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Oxiban 3mg tablet
	Composition	Each tablet contains: Oxybutynin Hydrochloride…3mg
	Diary No. Date of R & I & fee	Dy. No. 17457 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901428 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Drugs for urinary frequency and incontinence ATC Code: G04BD04
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Oxybutynin Hydrochloride Tablets 3mg approved by MHRA
	Me-too status	Oxynin Tablet Reg. No. 30227 Mfg. by M/s. Venus Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	

1057.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Nebcard 2.5mg tablet
	Composition	Each tablet contains: Nebicolol (as HCl)…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 17428 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901408 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Beta blocking agents, selective ATC Code: C07AB12
	Type of Form	Form-5
	Finished product Specification	Rotex Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nebivolol 2.5mg tablets approved by MHRA
	Me-too status	Byscard 2.5mg tablet Reg. No. 71104 Mfg. by M/s. The Searle Company
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1058.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Flunex 100mg tablet
	Composition	Each tablet contains: Nitrofurantoin…100mg
	Diary No. Date of R & I & fee	Dy. No. 17434 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901429 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Nitrofuran derivatives ATC Code: J01XE01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nitrofurantoin 100mg tablet approved by MHRA
	Me-too status	Urotoin 100mg Tablet Reg. No. 98424 Mfg. by M/s. Highnoon Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1059.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Flocin 200mg tablet
	Composition	Each tablet contains: Ofloxacin…200mg
	Diary No. Date of R & I & fee	Dy. No. 17423 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901403 dated 06-03-2019, endorsed on 06.03.2019.
	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 tablets approved by MHRA
	Me-too status	Myobid 200mg Tablet Reg. No. 44643 Mfg.by M/s. Panacea Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1060.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Myoson 50mg tablet
	Composition	Each tablet contains: Eperisone HCl…50mg
	Diary No. Date of R & I & fee	Dy. No. 17458 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0815562 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Other centrally acting agents ATC Code: M03BX09
	Type of Form	Form-5
	Finished product Specification	Rotex specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Eperisone hydrochloride tablets 50 mg approved by PMDA Japan
	Me-too status	Erip-son Tablet 50mg Reg. No. 103075 Mfg. by M/s. Wellmark Pharmaceuticlas
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required. ii. Firm has claimed in-house specifications. iii. Revised label claim as Film coated tablet as per reference product with submission of applicable fee is required.
	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.	
1061.	Name and address of manufacturer/ Applicant	M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Dinom 50mg tablet
	Composition	Each tablet contains: Dimenhydrinate…50mg
	Diary No. Date of R & I & fee	Dy. No. 17436 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901409 dated 06-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Aminoalkyl ethers ATC Code: R06AA11
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dimenhydrinate 50mg tablets approved by MHRA
	Me-too status	Danate 50mg Tablet Reg. No. 103291 Mfg. by M/s. Danas Pharma
	GMP status	Not Provided
	Remarks of the Evaluator	i. Latest GMP certificate/inspection report of M/s Rotex Pharma conducted within last 03 years is required.

	Decision: Deferred for the updated status of GMP of the firm from the QA&LT divison.

Agenda of Deputy Director PE&R (Mr. Muneeb Ahmed)

1062.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2948 dated 31.01.2022
	Details of fee submitted	Rs.30,000/- dated 13.01.2022
	The proposed proprietary name / brand name	VALTRIL TABLETS 50MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril/ Valsartan……24mg/ 26mg
	Pharmaceutical form of applied drug	Solid Dosage Form (Tablet)
	Pharmacotherapeutic Group of (API)	**Sacubitril:** A neprilysin inhibitor, antihypertensive drug. **Valsartan**: Angiotensin II Antagonist
	Reference to Finished product specifications	As per innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ENTRESTO Tablets by US FDA
	For generic drugs (me-too status)	Savesto 50mg tablet by Getz Pharma (Pvt) Ltd.
	GMP status of the Finished product manufacturer	Last inspection report dated 14-10-2021 concluded good level of cGMP compliance.
	Name and address of API manufacturer.	**Zhuhai Rundu Pharmaceutical Co., Ltd.** No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, P. R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, 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 General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.

	Stability studies	**Sacubitril/Valsartan** 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 **Batch No** / **Accelerated** / **Long Term** 57317080101 / 6 Months / 36 Months 57317080102 / 6 Months / 36 Months 57317080103 / 6 Months / 36 Months
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is UPERIO 50mg Tablet by Novartis Pharma by performing quality tests (Identification, Assay, Dissolution) CDP has been performed against the same brand that is Savesto 50mg Tablet by Getz Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

STABILITY STUDY DATA

Manufacturer of API	**Sacubitril/Valsartan** **Zhuhai Rundu Pharmaceutical Co., Ltd.** No.6, North Airport Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province, P.R.of China		
API Lot No.	57319070802		
Description of Pack (Container closure system)	Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 20, 24(Months)		
Batch No.	SVL/ 001	SVL/002	SVL/003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	07-06-2020	08-06-2020	09-06-2020
No. of Batches	03		

<table>
<tr><th colspan="3">Administrative Portion</th></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td>Firm has referred to onsite inspection report of their product:

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole)

which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June , 2021.
Registration Board decided to approve registration of

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole)

by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following two observations were reported in the report:
ix. The HPLC software is 21 CFR compliant.
x. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available.
xi. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
xii. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg.
Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Sacubitril/Valsartan

Firm had provided valid GMP and DML Certificate of
Zhuhai Rundu Pharmaceutical Co., Ltd. Issued by Drugs Control Administration Government of China,
GMP Valid up to: 15-09-2026
DML Valid up to: 10-12-2025</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted.
Sacubitril/Valsartan

<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>57319070802</td><td>JF20191104-1</td><td>1.5 kgs</td><td>05-12-2019</td></tr>
</table>
</td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms,
Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
</table>

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

Remarks of Evaluator:
In response to the DRAP letter No. F.1-1/2022/PEC-DRAP dated 09.03.2023, the firm submitted reply vide Dy. No. 7054 dated 10.03.2023. The firm has rectified the shortcomings communicated vide aforesaid letter. Except where the firm was requested to pro vide justification for using wet granulation method for formulation development, as the innovator is performing the dry granulation roller compaction process. In response the firm submitted that they are using wet granulation method with IPA for enhancing tablet compressibility.

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.**

1063.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd., Plot no. 33 Sundar Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd., Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2949 dated 31.01.2022
	Details of fee submitted	Rs.30,000/- dated 13.01.2022
	The proposed proprietary name / brand name	VALTRIL TABLETS 100MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-coated Tablet Contains: Sacubitril /Valsartan……48.6mg /51.4mg
	Pharmaceutical form of applied drug	Oral (Tablet)
	Pharmacotherapeutic Group of (API)	**Sacubitril:** A neprilysin inhibitor, antihypertensive drug. **Valsartan**: Angiotensin II Antagonist
	Reference to Finished product specifications	As per innovator Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ENTRESTO Tablets by US FDA
	For generic drugs (me-too status)	Uperio 100mg tablet by Novartis Pharma (Pvt) Ltd.

<table>
<tr><td></td><td>GMP status of the Finished product manufacturer</td><td>Last inspection report dated 14-10- concluded good level of cGMP compliance.</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Zhuhai Rundu Pharmaceutical Co., Ltd.

No.6, North Airport Road, Sanzao Town, Jinwan District,Zhuhai City, Guangdong Province, P.R.of 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 structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, 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 has submitted detail of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.</td></tr>
<tr><td></td><td>Stability studies</td><td>Sacubitril/Valsartan
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
<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>57317080101</td><td>6 Months</td><td>36 Months</td></tr>
<tr><td>57317080102</td><td>6 Months</td><td>36 Months</td></tr>
<tr><td>57317080103</td><td>6 Months</td><td>36 Months</td></tr>
</table></td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Pharmaceutical Equivalence have been established against the brand leader that is UPERIO 100mg Tablet by Novartis Pharma by performing quality tests (Identification, Assay, Dissolution) CDP has been performed against the same brand that is in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td>Sacubitril/Valsartan
Zhuhai Rundu Pharmaceutical Co., Ltd.
No.6, North Airport Road, Sanzao Town, Jinwan District,Zhuhai City, Guangdong Province, P.R.of China</td></tr>
<tr><td colspan="2">API Lot No.</td><td>57319070802</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td>Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td>Real time: 30˚C ± 2˚C / 65% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH</td></tr>
</table>

<table>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 8, 12, 16, 20, 24(Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>SVM/001</td><td>SVM/002</td><td>SVM/003</td></tr>
<tr><td colspan="2">Batch Size</td><td>1000 Tablets</td><td>1000 Tablets</td><td>1000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>06-2020</td><td>06-2020</td><td>06-2020</td></tr>
<tr><td colspan="2">Date of Initiation</td><td>25-04-2020</td><td>28-04-2020</td><td>30-04-2020</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Firm has referred to onsite inspection report of their product:

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules
(Dexlansoprazole)

which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021.
Registration Board decided to approve registration of

EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)

Dayzol 30mg Capsules, Dayzol 60mg Capsules
(Dexlansoprazole)

by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following two observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
iv. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg.
Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Sacubitril/Valsartan
Zhuhai Rundu Pharmaceutical Co., Ltd.
Firm had provided valid GMP and DML Certificate of

GMP Valid upto: 15-09-2026
DML Valid upto: 10-12-2025</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted.
Sacubitril/Valsartan
<table>
<tr><td>Batch No.</td><td>Invoice No.</td><td>Quantity Imported</td><td>Date of approval by DRAP</td></tr>
<tr><td>57319070802</td><td>JF20191104-1</td><td>1.5 kgs</td><td>05-12-2019</td></tr>
</table></td></tr>
</table>

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

Remarks of Evaluator:
In response to the DRAP letter No. F.1-1/2022/PEC-DRAP dated 09.03.2023, the firm submitted reply vide Dy. No. 7054 dated 10.03.2023. The firm has rectified the shortcomings communicated vide aforesaid letter. Except where the firm was requested to provide justification for using wet granulation method for formulation development, as the innovator is performing the dry granulation roller compaction process. In response the firm submitted that they are using wet granulation method with IPA for enhancing tablet compressibility.

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.**

1064.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd., Plot no. 33 Sundar Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd., Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2950 dated 31.01.2022
	Details of fee submitted	Rs.30,000/- dated 13.01.2022
	The proposed proprietary name / brand name	VALTRIL TABLETS 200MG
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-coated Tablet Contains: Sacubitril/ Valsartan ….97.2mg/ 102.8mg)
	Pharmaceutical form of applied drug	Solid Dosage Form (Tablet)
	Pharmacotherapeutic Group of (API)	**Sacubitril:** A neprilysin inhibitor, antihypertensive drug. **Valsartan**: Angiotensin II Antagonist
	Reference to Finished product specifications	As per innovator Specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ENTRESTO Tablets by US FDA
	For generic drugs (me-too status)	Uperio 200mg tablet by Novartis Pharma (Pvt) Ltd.
	GMP status of the Finished product manufacturer	Last inspection report dated 14-10-2021 concluded good level of cGMP compliance.
	Name and address of API manufacturer.	**Zhuhai Rundu Pharmaceutical Co., Ltd.** No.6, North Airport Road, Sanzao Town, Jinwan District,Zhuhai City, Guangdong Province, P.R.of China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, 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 General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.
	Stability studies	**Sacubitril/Valsartan** 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
	Module-III (Drug Product):	The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is UPERIO 200mg Tablet by Novartis Pharma by performing quality tests (Identification, Assay, Dissolution) CDP has been performed against the same brand that is in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)
	Analytical method validation/verification of product	Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.

Batch No	**Accelerated**	**Long Term**
57317080101	6 Months	36 Months
57317080102	6 Months	36 Months
57317080103	6 Months	36 Months

STABILITY STUDY DATA	
Manufacturer of API	**Sacubitril/Valsartan** **Zhuhai Rundu Pharmaceutical Co., Ltd.** No.6, North Airport Road, Sanzao Town, Jinwan District,Zhuhai City, Guangdong Province, P.R.of China
API Lot No.	57319070802

Description of Pack (Container closure system)		Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 20, 24(Months)		
Batch No.		SVH/001	SVH/002	SVH/003
Batch Size		1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date		06-2020	06-2020	06-2020
Date of Initiation		02-06-2020	03-06-2020	04-06-2020
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June , 2021. Registration Board decided to approve registration of EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: i. The HPLC software is 21 CFR compliant. ii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well. iv. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg. Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sacubitril/Valsartan** **Zhuhai Rundu Pharmaceutical Co., Ltd.** Firm had provided valid GMP and DML Certificate of GMP Valid upto: 15-09-2026 DML Valid upto: 10-12-2025		

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted. **Sacubitril/ Valsartan**

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
57319070802	JF20191104-1	1.5 kgs	05-12-2019

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

Remarks of Evaluator:
In response to the DRAP letter No. F.1-1/2022/PEC-DRAP dated 09.03.2023, the firm submitted reply vide Dy. No. 7054 dated 10.03.2023. The firm has rectified the shortcomings communicated vide aforesaid letter. Except where the firm was requested to provide justification for using wet granulation method for formulation development, as the innovator is performing the dry granulation roller compaction process. In response the firm submitted that they are using wet granulation method with IPA for enhancing tablet compressibility.

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.**

1065.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore, Pakistan.**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, 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. 1744 dated: 19.01.2022
	Details of fee submitted	Deposit slip No. 51989182 PKR 30,000/-: dated 28/12/2021
	The proposed proprietary name / brand name	**VELVET-S 49/51MG FILM COATED TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril……49mg Valsartan……..…...51mg (as Sacubitril Valsartan Sodium Salt Complex)
	Pharmaceutical form of applied drug	Yellow colored, oblong biconvex tablet with score line one side.

		Film coated oral tablet
	Pharmacotherapeutic Group of (API)	Valsartan: Angiotensin II receptor Antagonist Sacubitril: Neprilysin inhibitor
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	07's, 14's, 28's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto 49 mg/51 mg film-coated tablets, Novartis Pharmaceuticals UK Limited, UK approved.
	For generic drugs (me-too status)	1. Savesto 100mg (49/51 mg) of M/s Getz Pharma (Pvt) Ltd, Karachi. 2. Valsatril 100 (49/51 mg) of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status of the Finished product manufacturer	GMP certificate granted on 02/06/2022 Tablet (General), Capsule (General), Oral liquid (General), Cream and Ointment (General) & General Antibiotic) sections are approved.
	Name and address of API manufacturer.	Sacubitril-Valsartan Complex Nantong Chanyoo Pharmatech Co., Ltd, China LCZ696 In-House Specifications
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T0005TAT, T0006TAT, T0007TAT)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Entresto 49/51mg Tablet by Novartis Pharma Limited by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Entresto Tablet by Novartis Pharma Limited in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found

		satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Sacubitril-Valsartan Complex Nantong Chanyoo Pharmatech Co., Ltd, China **In-House Specifications**		
API Lot No.	API Batch No. RD-LCZ696-202010101		
Description of Pack (Container closure system)	The proposed pack size of Velvet- S Tablet 49/51mg is 1x14's in Alu—Alu Blister.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T0005TAT	T0006TAT	T0007TAT
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	04-2021	05-2021	05-2021
Date of Initiation	28-05-2021	28-05-2021	28-05-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Velvet-S 49/51mg Film Coated Tablet
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Nantong Chanyoo Pharmatech Co, Ltd, Yangkou Chemical Industrial Park, Rundong Coastal Economic Development Zone, China. Manufacturing License No.Su 2016512
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**COA of Batch No.** RD-LCZ696-202010101 of API (Valsartan/Sacubitril) of both Drug Substance manufacturer and Drug Product manufacturer is provided.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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.**

1066.	Name, address of Applicant / Marketing Authorization Holder	**M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore, Pakistan.**

	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, 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. 1743 dated 19.01.2022
	Details of fee submitted	Deposit slip No. 390635913 PKR 30,000/-: dated 28/12/2021
	The proposed proprietary name / brand name	**VELVET-S 97/103MG FILM COATED TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Sacubitril…….97mg Valsartan…….103mg (as Sacubitril Valsartan Sodium Salt Complex)
	Pharmaceutical form of applied drug	Green colored, oblong biconvex tablet with score line one side. Film coated oral tablet
	Pharmacotherapeutic Group of (API)	Valsartan: Angiotensin II receptor Antagonist Sacubitril: Neprilysin inhibitor
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	07's, 14's, 28's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Entresto 97mg/103mg film-coated tablets, Novartis Pharmaceuticals UK Limited, UK approved.
	For generic drugs (me-too status)	1. Savesto 200mg (97/103 mg) of M/s Getz Pharma (Pvt) Ltd, Karachi. 2. Valsatril 200mg (97/103 mg) of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status of the Finished product manufacturer	GMP certificate granted on 02/06/2022 Tablet (General), Capsule (General), Oral liquid (General), Cream and Ointment (General) & General Antibiotic) sections are approved.
	Name and address of API manufacturer.	Sacubitril-Valsartan Complex Nantong Chanyoo Pharmatech Co., Ltd, China LCZ696 In-House Specifications
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of

		drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-0001TAU, T-0002TAU, T-0003TAU)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Entresto 97/103mg Tablet by Novartis Pharma Limited by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Entresto Tablet by Novartis Pharma Limited in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Sacubitril-Valsartan Complex Nantong Chanyoo Pharmatech Co., Ltd, China **In-House Specifications**		
API Lot No.	API Batch No. RD-LCZ696-202010101		
Description of Pack (Container closure system)	The proposed pack size of Velvet- S Tablet 97/103mg is 1x14's in Alu—Alu Blister.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**T-0001TAU**	**T-0002TAU**	**T-0003TAU**
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	02-06-2021	14-06-2021	14-06-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Velvet-S 24/26mg Film Coated Tablet approved in 322 Minutes of Meeting.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Nantong Chanyoo Pharmatech Co, Ltd, Yangkou Chemical Industrial Park , Rundong Coastal Economic Development Zone, China. Manufacturing License No.Su 2016512
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**COA of Batch No.** RD-LCZ696-202010101 of API (Valsartan/Sacubitril) of both Drug Substance manufacturer and Drug Product manufacturer is provided.

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

Remarks of Evaluator:

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.**

1067.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd, Plot no. 33 Sundar Industrial Estate Lahore.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd, Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3115 dated 31.02.2022
	Details of fee submitted	Rs.75,000/- dated 25.01.2022
	The proposed proprietary name / brand name	**VONZ-A 100/10MG TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Aspirin……...100mg Vonoprazan as Fumarate ……10mg
	Pharmaceutical form of applied drug	Oral solid dosage form
	Pharmacotherapeutic Group of (API)	**Aspirin:** Analgesics, antipyretics and Platelet-aggregation Inhibitors.
		Vonoprazan Fumarate: First-in-class potassium-competitive acid blocker, Proton Pump Inhibitor
	Reference to Finished product specifications	As Per Innovator Specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Cabpirin Tablets** 100/10mg approved by **PMDA Japan**
	For generic drugs (me-too status)	N/A (as it is New Drug Product)
	GMP status of the Finished product manufacturer	Last inspection report dated 14.10.2021 concluded good level of cGMP compliance.

<table>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Aspirin: JQC (Huayin) Pharmaceutical Co., Ltd. Yuquan Road, Huayin City, Shanxi province, P.R. of China.</td><td>Vonoprazan Fumarate: Ami Lifesciences Private Limited Block No.82/B, ECP Road, At & Post: Karakhadi-391450, Taluka: Padra, District: Vadodara Gujarat, INDIA.</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td colspan="2">Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, 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 colspan="2">The firm as submitted detail of general information, general properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.</td></tr>
<tr><td></td><td>Stability studies</td><td colspan="2">Stability study conditions:
Real time: 30˚C ± 2˚C / 65% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Aspirin:
<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>A201104081</td><td>6 Months</td><td>48 Months</td></tr>
<tr><td>A201104082</td><td>6 Months</td><td>48 Months</td></tr>
<tr><td>A201104083</td><td>6 Months</td><td>48 Months</td></tr>
</table>
Vonoprazan Fumarate:
<table>
<tr><th>Batch No</th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>VPF/30021020</td><td>6 Months</td><td>60 Months</td></tr>
<tr><td>VPF/30031020</td><td>6 Months</td><td>60 Months</td></tr>
<tr><td>VPF/30041020</td><td>6 Months</td><td>60 Months</td></tr>
</table></td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td colspan="2">The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , Characterization of impurities, reference standard or impurities, Container closure and stabilities studies.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td colspan="2">Pharmaceutical Equivalence have been established against the brand leader that is Cabpirin 100/10mg Tablet by performing quality tests (Identification, Assay, and Dissolution. CDP has been performed against the same brand that is in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8)</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td colspan="2">Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and peak range.</td></tr>
<tr><td colspan="4">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td>Aspirin:</td><td>Vonoprazan Fumarate:</td></tr>
</table>

		JQC (Huayin) Pharmaceutical Co., Ltd.	Ami Lifesciences Private Limited.
API Lot No.		A2108011	VPF/30010821M
Description of Pack (Container closure system)		A Film Coated modified release White color, round shape, biconvex tablet Plain at both sides packed in Alu-Alu blister.	
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24(Months)	
Batch No.		**AV-001**	**AV-002**
Batch Size		5000 Tab	5000 Tab
Manufacturing Date		10-2021	10-2021
Date of Initiation		26-10-2021	28-10-2021
No. of Batches		02	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June , 2021. Registration Board decided to approve registration of EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: The HPLC software is 21 CFR compliant. i. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. ii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well. iii. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg. Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e., not less than 80% (Q) in 15minutes at initial and 01-month time point.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued	**Aspirin:**	**Vonoprazan Fumarate:**

<table>
<tr><td></td><td>by concerned regulatory authority of country of origin.</td><td>Firm had provided valid GMP & DML Certificate of JQC (Huayin) Pharmaceutical Co., Ltd. China
DML Valid upto: 12- 16- 2025
GMP Valid upto: 11- 01- 2023</td><td>Firm had provided valid GMP & DML Certificate of Ami Lifesciences Private Limited, India
DML Valid upto: 14-06- 2025
GMP Valid upto: 24-04- 2022</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted
<table>
<tr><th>Name of API</th><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>Aspirin:</td><td>A2108011</td><td>20210710 01</td><td>1.5Kg</td><td>06-10-2021</td></tr>
<tr><td>Vonoprazan Fumarate:</td><td>VPF/30010821M</td><td>ALPL/Sample-00190/20-21</td><td>800 gm</td><td>14-09-2021</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms,
Raw data sheets, COA, summary data sheets etc.</td><td colspan="2">Submitted</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td colspan="2">Audit trail reports have been submitted.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td colspan="2">Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
<tr><td colspan="4">Remarks of Evaluator:</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td>1068.</td><td>Name, address of Applicant / Marketing Authorization Holder</td><td colspan="2">M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad, Pakistan</td></tr>
<tr><td></td><td>Name, address of Manufacturing site.</td><td colspan="2">M/s Scotmann Pharmaceuticals,
5-D, I-10/3, Industrial Area, Islamabad, Pakistan</td></tr>
<tr><td></td><td>Status of the applicant</td><td colspan="2">☒ Manufacturer
☐ Importer
☐ Is involved in none of the above (contract giver)</td></tr>
<tr><td></td><td>Status of application</td><td colspan="2">☐ New Drug Product (NDP)
☒ Generic Drug Product (GDP)</td></tr>
<tr><td></td><td>Intended use of pharmaceutical product</td><td colspan="2">☒ Domestic sale
☐ Export sale
☐ Domestic and Export sales</td></tr>
<tr><td></td><td>Dy. No. and date of submission</td><td colspan="2">Dy. No. 2951 dated 28/01/2022</td></tr>
</table>

	Details of fee submitted	PKR 30,000/- dated 27/12/2021
	The proposed proprietary name / brand name	**ESONAP DR TABLETS 375/20MG**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Release Tablet contains: Naproxen……..…. 375mg Esomeprazole as magnesium trihydrate …… 20mg
	Pharmaceutical form of applied drug	Delayed release Tablet
	Pharmacotherapeutic Group of (API)	Naproxen: Non-steroidal anti-inflammatory drug Esomeprazole: Proton pump inhibitor
	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	Vimovo DR Tablets Manufacturer Horizon Pharma
	For generic drugs (me-too status)	Glomov Tablets 375/20mg Manufactured by Global Pharmaceuticals DRAP Registration no. 109339
	GMP status of the Finished product manufacturer	GMP certificate was granted on 17/12/2020, Tablet section approved.
	Name and address of API manufacturer.	Naproxen: **Name:** Industrias Químicas Falcon de México, S.A. de C.V **Address:** Km. 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec, Morelos, México **FEI Number:** 3002808297 **DUNS Number:** 812915445 **Phone No:** +52-777-329-3400 **Fax No.:** +52-777-321-0117 **Email: hector.almanza@drreddys.com** Esomeprazole Magnesium Trihydrate: **Name:** Everest Organics Limited **Address:** Aroor Village, Sadasivpet (Mandal), Sangareddy (District), Telangana, India. **Phone:** 91-8455-250186, 250113/115 **Fax:** 91-8455-250114
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Naproxen and Esomeprazole Magnesium Trihydrate is present in USP Pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance of both API's separately.

	Stability studies	Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T-01, T-02, T-03)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its 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 Glomov Tablets 375/20mg by Global Pharmaceuticals, Islamabad performing quality tests (Identification, Physical appearance, Dissolution, Assay).
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, Robustness, accuracy, precision (Repeatability), specificity.

STABILITY STUDY DATA

Manufacturer of API	Naproxen: **Name:** Industrias Químicas Falcon de México, S.A. de C.V **Address:** Km. 4.5 Carretera Federal Cuernavaca-Cuautla 62578 Jiutepec, Morelos, México **FEI Number:** 3002808297 **DUNS Number:** 812915445 **Phone No:** +52-777-329-3400 **Fax No.:** +52-777-321-0117 **Email: hector.almanza@drreddys.com** Esomeprazole Magnesium Trihydrate: **Name:** Everest Organics Limited **Address:** Aroor Village, Sadasivpet (Mandal), Sangareddy (District), Telangana, India. **Phone:** 91-8455-250186, 250113/115 **Fax:** 91-8455-250114		
API Lot No.	Naproxen: ANMA000240 Esomeprazole Magnesium Trihydrate: ESM/E-108/19		
Description of Pack (Container closure system)	The primary packaging material is Alu-Alu blister with cold aluminum foil. The material complies with Ph. Eur. and EC requirements. (7's, 10's, 14's, 20's, 28's & 30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: Initial, 3, 6 (Months) Real time: Initial, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	07-02-2020	09-02-2020	11-02-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Velscot Tablets 400mg/100mg containing Sofosbuvir 400mg and Velpatasvir 100mg DRAP Registration no. 087777
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Naproxen: Copy of GMP certificate No. 183300516A0534 issued by Comision Federal Para La Proteccion Contra Riesgos Sanitarios Esomeprazole Magnesium Trihydrate: Copy of GMP certificate No. 42005/TS/2020 issued by Drug Control Administration, Government of Telangana Issue & Valid Upto Dt: 30-07-2020- 30/07/2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 of Naproxen: Dated: 20/11/2019 Form-6 of Esomeprazole Magnesium Trihydrate: Dated: 29/01/2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	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
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.**		
1069.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1657 dated 16.01.2022
	Details of fee submitted	Rs. 50000/- dated 14.04.2021
	The proposed proprietary name / brand name	**AZILTA 40MG TABLET**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….40mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.

	Reference to Finished product specifications	Innovator's
	Proposed Pack size	2×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 40mg tablet by M/s Takeda Ireland Ltd.
	For generic drugs (me-too status)	
	GMP status of the Finished product manufacturer	GMP inspection dated 10.012.2020 recommended grant of GMP certificate.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azilsartan Medoxomil is not present in BP and USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T-043, T-044 and T-045.)
	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 that is **Edarbi 40mg tablet by M/s Takeda Ireland Ltd** performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Edarbi 40mg tablet by M/s Takeda Ireland Ltd**
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
Manufacturer of API	CTX Lifesciences (P) Ltd. India	
API Lot No.	19AK00006	
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×14's)	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	

Strength		80mg/Tablet	
Batch No.		T-046	T-047	T-048
Batch Size		1200 tab	1200 tab	1200 tab
Manufacturing Date		04-2020	04-2020	04-2020
Date of Initiation		14-04-2020	14-04-2020	14-04-2020
No. of Batches		03	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate vide No. 1705118 valid till 28.05.2019 issued by FDCA Gujarat Estate India	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice no. EI/3092100101 attested by AD I&E DRAP, Peshawar, dated 16-05-2019	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Evaluator:			
Decision: Approved with Innovator's specifications. • **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.**			
1070.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceutical Industrial Estate Hattar Haripur Kpk Pakistan.**	
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceutical Plot No. 122 Phase 5, Industrial Estate Hattar Haripur Kpk Pakistan.	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 1657 dated 16.01.2022	
	Details of fee submitted	Rs. 50000/- dated 14.04.2021	
	The proposed proprietary name / brand name	**AZILTA 80MG TABLET**	

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan Medoxomil (as Potassium) …….80mg
	Pharmaceutical form of applied drug	White to off white biconvex round shape Tablets.
	Pharmacotherapeutic Group of (API)	**Angiotensin II receptor antagonists**.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	2×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi 80mg tablet by M/s Takeda Ireland Ltd.
	For generic drugs (me-too status)	
	GMP status of the Finished product manufacturer	GMP inspection dated 10.012.2020 recommended grant of GMP certificate.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azilsartan Medoxomil is not present in BP and USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-043, T-044 and T-045.)
	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 that is **Edarbi 80mg tablet by M/s Takeda Ireland Ltd** performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Edarbi 80mg tablet by M/s Takeda Ireland Ltd**
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
Manufacturer of API	CTX Lifesciences (P) Ltd. India	
API Lot No.	19AK00006	
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×14's)	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Strength	80mg/Tablet		
Batch No.	T-046	T-047	T-048
Batch Size	1200 tab	1200 tab	1200 tab
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	14-04-2020	14-04-2020	14-04-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate vide No. 1705118 valid till 28.05.2019 issued by FDCA Gujarat Estate India
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice no. EI/3092100101 attested by AD I&E DRAP, Peshawar, dated 16-05-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved with Innovator's specifications.

- **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.**

1071.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Le Mendoza Pharmaceutical (Pvt.) Ltd. Plot No. 7, Sector 23, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32575 Dated 30.11.2021

	Details of fee submitted	PKR 20,000/= 04.05.2021 Slip # 1905588 PKR 10,000/=31.08.2021 Slip # 8319810296
	The proposed proprietary name / brand name	**Meditol Disinfectant Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Contains: Chloroxylenol BP……. 4.8% w/v
	Pharmaceutical form of applied drug	Brown solution free from foreign particles with characteristic odour of pine.
	Pharmacotherapeutic Group of (API)	Disinfectant
	Reference to Finished product specifications	BP
	Proposed Pack size	50ml, 100ml, 500ml & 1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dettol by M/s Reckitt Benckiser, USFDA Approved.
	For generic drugs (me-too status)	Kemydol by M/s Al Kemy (Pvt.) Ltd., Reg. No. 021515.
	GMP status of the Finished product manufacturer	
	Name and address of API manufacturer.	M/s Jiangsu Huanxin High-Tech Materials Co., Ltd., China. North Wei'er Road, Bio -Tech Zone, Dafeng Harbor, Dafeng, 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)	Official monograph of chloroxylenol is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TB-001, TB-002, TB-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	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 Jiangsu Huanxin High-Tech Materials Co., Ltd., China.		
API Lot No.	20050806		
Description of Pack (Container closure system)	A PVC plastic bottle closed with a plastic HDPE cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 36 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	TB-001	TB-002	TB-003
Batch Size	20 Liter	20 Liter	20 Liter
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	12-06-2018	13-06-2018	14-06-2018
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Manufacturing Licence No. 913209007615191149.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The method is UV based.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Stability Data is attached.

Remarks of Evaluator:
As per Licensing Division approval dated 26.10.2020 the firm do not possess external liquid preparation manufacturing facility.

Decision: Registration Board rejected the application since firm does not possess required manufacturing facility of "External liquid preparation" section.

1072.	**Name, address of Applicant / Importer**	**M/s Sohail Corporation Plot No. 474 Siraj Colony Moosa Lane Karachi.**
	Details of Drug Sale License of importer	Drug License by the way of wholesale vide No. DHODSK(Drug)/-433/- dated 01.012.2020 valid till 19-11-2022
	Name and address of marketing authorization holder (abroad)	M/s Anhui Chengsi Pharmaceuticals Co., Ltd, No. 5068 Huaishang Road Bengbu Anhui China.
	Name, address of manufacturer(s)	M/s Anhui Chengsi Pharmaceuticals Co., Ltd, No.

		5068 Huaishang Road Bengbu Anhui China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Legalized CoPP vide No. Anuhi 20210048 issued by Anhui Medical Products Administration China dated 07.02.2021 valid till 06.02.2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of agency agreement.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	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. 30798 dated 10.11.2021
	Details of fee submitted	PKR 100000/- dated 07.04.2021 and 50000/- dated 07.06.2021.
	The proposed proprietary name / brand name	**Gentamicin Sulfate Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule of 2ml contains: Gentamicin Sulfate …….80mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antibiotic (Lincosamide antibacterial)
	Reference to Finished product specifications	BP
	Proposed Pack size	1's Ampoule
	Proposed unit price	Not submitted
	The status in reference regulatory authorities	Gentamicin Injection MHRA approved.
	For generic drugs (me-too status)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Yantai Justaware Pharmaceutical Co., Ltd No. 1 Yanfu Road Zhifu District Yantai City Shandong Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API conducted at accelerated conditions 40°C ±2°C / 75% ± 5% RH for 6 months as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C / 60 ± 5% RH & 30°C ± 2°C / 75 ± 5% RH. The stability study data is for 9 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence with 5 chines manufactured products is submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Low Borosilicate glass
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 75% ± 5% RH. The real time stability study data of 3 batches is for 34 months
Decision:	**Approved as per policy of inspections of manufacturer abroad.**	

1073.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceutical plot 122, Block-B Phase 5 industrial estate Hattar KPK, Pakistan**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceutical plot 122, Block-B Phase 5 industrial estate Hattar KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2368 dated 25.01.2022
	Details of fee submitted	Rs. 30000/- dated 21.10.2021
	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 as Propanediol Monohydrate ……5mg
	Pharmaceutical form of applied drug	Yellow color 6mm round shaped bisected one side other plain film coated tablets.
	Pharmacotherapeutic Group of (API)	**Anti-Diabetic**
	Reference to Finished product specifications	Product Complies Innovator's Specs

	Proposed Pack size	1×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Forxiga Tablet , USFDA Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet Hilton Pharma, Karachi Reg. No. 089367
	GMP status of the Finished product manufacturer	GMP certificate issued on 23.11.2021 by DRAP peshawer
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical CO. Ltd Address: Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province-123000,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	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: (160220), (DG 160124) (160108)
	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 Dapa 5mg tablet by Hilton Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Dapa 5mg Tablet by Hilton Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Fuxin Long Rui Pharmaceutical CO. Ltd Address: Fluoride Industrial Park,Fumeng County(Yi MaTu),FuxinCity,Liaoning Province 123000,China
API Lot No.	DG-20170722-D01-DG06-01

Description of Pack (Container closure system)	14's tablets per pack in alu alu Blister packed in Unit carton with a leaflet		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DG01	DG02	DG03
Batch Size	300 tab	300 tab	300 tab
Manufacturing Date	12-2020	12-2020	12-2020
Date of Initiation	21-12-2020	22-12-2020	23-12-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	DML issued by FDA Liaoning Province China dated 21.12.2017 valid 20.12.2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	100gm of Dapagliflozin API approval is granted by DRAP Peshawar dated 09.01.2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved with Innovator's specifications.

- **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.**

1074.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Standpharm Pakistan (Pvt) Ltd, 20 Km, Ferozpur Road, Lahore**
	Name, address of Manufacturing site.	M/s Standpharm Pakistan (Pvt) Ltd, 20 Km, Ferozpur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 20050 dated 16-07-2021
	Details of fee submitted	PKR 20,000/- dated: 30/03/2021 Differential fee PKR 10,000/- dated: 12/05/2022. Slip No. 838513201025.
	The proposed proprietary name / brand name	**Monocor 2.5mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Bisoprlol Fumarate …… 2.5mg
	Pharmaceutical form of applied drug	Blue colored oblong shaped tablets, one side is plain and bisect line on other side
	Pharmacotherapeutic Group of (API)	Antihypertensive (beta blocker)
	Reference to Finished product specifications	USP
	Proposed Pack size	1x 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cardicor 2.5mg tablet by M/s Merck Serono Ltd, MHRA (UK) Approved.
	For generic drugs (me-too status)	Concor 2.5mg Tablets by M/s Martin Dow Marker Ltd. (Reg. No. 028000).
	GMP status of the Finished product manufacturer	Standpharm Pakistan (Pvt) Ltd: GMP Inspection report conducted on 18-02-2020 concluding satisfactory level of GMP compliance. GMP Certificate issued by DRAP on 29/09/2202 RefNo.147/2022-DRAP(AD-216189762).
	Name and address of API manufacturer.	M/s Supriya Lifescience Ltd. 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East) Mumbai - 400 063. India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Bisoprolol Fumarate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches # : (25/13, 26/13, 27/13)
	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, verification of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against the Concor 2.5mg Tablets manufactured by Martin Dow Marker Ltd. Firm has submitted results of CDP for their product against Concor 2.5mg Tablets manufactured by Martin Dow Marker Ltd. Firm has performed CDP testing as per USP method. The values for tests are in the acceptable range. The results of all the tests of both products falls within the specifications and are comparable.
	Analytical method validation/verification of product	Method verification studies have submitted including specificity, accuracy, precision, repeatability, linearity and robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s Supriya Lifescience Ltd. 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East) Mumbai - 400 063. India.		
API Lot No.	SLL/BF/0619002		
Description of Pack (Container closure system)	Alu PVC blister packed in unit carton (1x14'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: 0,1,2,3,4,6,8,12,16,20,24, 26 weeks Real Time: 0,1,2,3,4,6,8,12,16,20,24, 26 weeks		
Batch No.	TRLM-001	TRLM-002	TRLM-003
Batch Size	10,000 tab	10,000 tab	10,000 tab
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	18-07-2019	22-07-2019	24-07-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Neon 2g IV Injection approved in 317th meeting of Registration Board (16-17 May 2022).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/103995/2021/11/38094 issued by Food & Drug Administration India valid till 23/11/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice No. SLL/E/19-20/320 dated 13/06/2019 DRAP Diary # 9434/19-06-19 Dispatch # 8609/21-06-19 specifying import of 5 kg of bisoprolol fumarate signed by AD-(I&E) Lahore office 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:

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.**

EXPORT FACILITATION:

1075.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 44 date of submission: 02-01-2023
	Details of fee submitted	PKR 30,000/-: dated 30-12-2022 Slip no. 8659851353
	The proposed proprietary name / brand name	**Eppra 100mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Levetiracetam….100mg
	Pharmaceutical form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP specs
	Proposed Pack size	60ml, 90ml & 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Keppra (Levetiracetam) 100 mg/ml oral solution of UCB Inc. (FDA approved)
	For generic drugs (me-too status)	Lerace 100mg Oral Solution of Hilton Pharma Pvt. Ltd.
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Name and address of API manufacturer.	**M/s Dhanuka laboratories Ltd.** Plot No. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO

		QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: Temp.: 30°C ± 2°C, RH: 65% ± 5% for 36 month Accelerated: Temp.: 40°C ± 2°C, RH: 75% ± 5%for 6 months Batches: (LTR-F#0001/15, LTR-F#0002/15, LTR-F#0003/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence of their developed formulation Eppra 100mg/ml Oral Solution (B #ST22E004) with comparator product Lerace Oral Solution (B #144844) of M/s Hilton Pharma Pvt Ltd. The results were found comparable with the reference product.
	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 Dhanuka laboratories Ltd.** Plot No. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.
API Lot No.	LTR- 2002008
Description of Pack (Container closure system)	Clear liquid free from foreign particles, filled in pet amber bottle with plastic seal and cap along with graduated oral

	syringe and an adapter for the syringe.	
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.	ST22E004	ST22E005
Batch Size	2000 Bottles	2000 Bottles
Manufacturing Date	05-2022	05-2022
Date of Initiation	07-05-2022	07-05-2022
No. of Batches	02	

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 GMP certificate No. DC/A-2/WHO GMP/2022 issued by Drugs Control Organization Swasthya Bhawan, Tilak Marg, Jaipur Valid till 27/01/2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of Levetiracetam (100 Kg, Invoice # SOK/EXP1920/0093 dated: 20-02-2020)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

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.**

1076.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.1052 dated 12.01.2023
	Details of fee submitted	PKR 30,000/-: dated 30-12-2022 Slip no. 919974835
	The proposed proprietary name / brand name	**EPPRA 500MG/5ML INJECTION**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Levetiracetam….100mg
	Pharmaceutical form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP specs
	Proposed Pack size	1's (Ampoule)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levetiracetam DESITIN ® concentrate for solution for infusion of Desitin Pharma GmbH, 4410 Liestal. (Swissmedic approved)
	For generic drugs (me-too status)	Lerace Injection of Hilton Pharma Pvt. Ltd.
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Name and address of API manufacturer.	**M/s Dhanuka laboratories Ltd.** Plot No. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: Temp.: 30°C ± 2°C, RH: 65% ± 5% for 36 month

		Accelerated: Temp.: 40°C ± 2°C, RH: 75% ± 5%for 6 months Batches: (LTR-F#0001/15, LTR-F#0002/15, LTR-F#0003/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence of their developed formulation Eppra 500mg/5ml Injection (B #ST22F002) with comparator product Lerace 500mg/5ml Injection (B #140242) of M/s Hilton Pharma Pvt Ltd. The results showed that both test and comparator products were comparable.
	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 Dhanuka laboratories Ltd.** Plot No. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.	
API Lot No.	LTR- 2002008	
Description of Pack (Container closure system)	A clear and colorless liquid free from foreign particles filled in clear glass ampoule, (1's)	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	ST22F002	ST22F003
Batch Size	2000 Ampoules	2000 Ampoules
Manufacturing Date	06-2022	06-2022
Date of Initiation	04-06-2022	04-06-2022
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 307th meeting decided to approve registration of Doribac Injection 250mg & 500mg. **Inspection date:** 8th and 11th January 2021 The report shows that:

		The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. DC/A-2/WHO GMP/2022/77 issued by Drugs Control Organization Swasthya Bhawan, Tilak Marg, Jaipur Valid till 27/01/2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of Leveritacetam (100 Kg, Invoice # SOK/EXP1920/0093 dated: 20-02-2020)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator:		
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.**		
1077.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.1553 dated : 17-01-2023
	Details of fee submitted	PKR 75,000/-: dated 30-12-2022 Slip no. 52852032065
	The proposed proprietary name / brand name	**EPPRA 500MG/5ML INJECTION**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Levetiracetam….100mg
	Pharmaceutical form of applied drug	Liquid Injection

	Pharmacotherapeutic Group of (API)	Anticonvulsants
	Reference to Finished product specifications	USP specs
	Proposed Pack size	1's (Vial)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	KEPPRA 500mg/5ml for infusion of UCB INC (FDA approved)
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Name and address of API manufacturer.	**M/s Dhanuka Laboratories Ltd.** Plot No. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: Temp.: 30°C ± 2°C, RH: 65% ± 5% for 36 month Accelerated: Temp.: 40°C ± 2°C, RH: 75% ± 5%for 6 months Batches: (LTR-F#0001/15, LTR-F#0002/15, LTR-F#0003/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence of their developed

		formulation Eppra 500mg/5ml Injection (B #ST22F008) with comparator product Lerace 500mg/5ml Injection (B #140242) of M/s Hilton Pharma Pvt Ltd. The results showed that both test and comparator products were comparable.
	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 Dhanuka Laboratories Ltd.** Plot No. SP4-4, Industrial Area, Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.	
API Lot No.	LTR- 2002008	
Description of Pack (Container closure system)	A clear and colorless liquid free from foreign particles filled in clear glass vial, (1's)	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	ST22F08	ST22F009
Batch Size	2000 vials	2000 vials
Manufacturing Date	06-2022	06-2022
Date of Initiation	09-06-2022	09-06-2022
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 307th meeting decided to approve registration of Doribac Injection 250mg & 500mg. **Inspection date:** 8th and 11th January 2021 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. DC/A-2/WHO GMP/2022/77 issued by Drugs Control Organization Swasthya Bhawan, Tilak Marg, Jaipur Valid till 27/01/2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of Levetiracetam (100 Kg, Invoice # SOK/EXP1920/0093 dated: 20-02-2020)

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

Remarks of Evaluator:

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.**

1078.	**Name and address of manufacturer / Applicant**	**M/s MTI Medical Private Limited, Plot No. 586,587 Sundar Industrial Estate Lahore**
	Brand Name +Dosage Form + Strength	Tobuject Lyophilized Injection 250mg/Vial
	Composition	Each vial contains: Dobutamine as HCl……250mg
	Diary No. Date of R& I & fee	Dy. No. 15215 dated 07/03/2019; PKR 50,000/-
	Pharmacological Group	Direct Acting Inotropic Agent
	Type of Form	Form-5D
	Finished product Specifications	USP
	Pack size & Demanded Price	1's Vial & As per PRC
	Approval status of product in Reference Regulatory Authorities	DOBUTREX 250 mg powder for injection Aspen Pharmacare Australia Pty Ltd Therapeutic Goods Administration **(TGA)**
	Me-too status (with strength and dosage form)	NA
	GMP status	GMP inspection conducted on 22-June-2022, GMP certificate grant on 22-August 2022. Tablet (General) section approved.
	Remarks of the Evaluator :	
	Now the firm has submitted stability data detailed as under:	

STABILITY STUDY DATA

Drug	Tobuject Lyophilized Injection 250mg/Vial
Name of Manufacturer	M/s MTI Medical Private Limited Plot#586,587 Sundar Industrial Estate Lahore
Manufacturer of API	M/s Pancsheel Organics Ltd B6/B7, sector C Sanwer road Industrial Estate India
API Lot No.	DBH/2122001 Mfg Date: Feb 2019 Exp Date: Jan 2023
Description of Pack (Container closure system)	Glass Vial
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH for 30 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)

<table>
<tr><td colspan="2">Batch No.</td><td>TJt-001</td><td>TJt-002</td><td>TJt-003</td></tr>
<tr><td colspan="2">Batch Size</td><td>500 vials</td><td>500 vials</td><td>500 vials</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>06-2019</td><td>06-2019</td><td>06-2019</td></tr>
<tr><td colspan="2">Date of Initiation</td><td>24-06-2019</td><td>28-06-2019</td><td>30-06-2019</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="2">Date of Submission</td><td colspan="3">31-3-2022</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td colspan="2">Documents To Be Provided</td><td colspan="3">Status</td></tr>
<tr><td>1</td><td>Reference of previous approval of applications with stability study data of the firm</td><td colspan="3">Colimate Injection 150mg approved in 324th meeting of Registration Board.</td></tr>
<tr><td>2</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td colspan="3">Copy of COA vide batch No. DBH/181907 mfg date 02.2019 and exp. date 01.2021 is submitted.</td></tr>
<tr><td>3</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer</td><td colspan="3">The firm has submitted method of analysis of API from both API Manufacturer and Finished Product manufacturer. Both will follow USP monograph.</td></tr>
<tr><td>4</td><td>Stability study data of API from API manufacturer</td><td colspan="3">Firm has submitted accelerated and real time stability data of three batches</td></tr>
<tr><td>5</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Firm has submitted copy of letter issued by FDA Madya Pardesh dated 28.02.2022 indicating License of M/s Pancsheel Organics Ltd B6/B7, Sector C Sanwer road Industrial Estate India is valid till 31.12.2026.</td></tr>
<tr><td>6</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">The firm has submitted copy of DRAP attested Invoice for Import of API vide DAP Dy. No. 5265 dated 27.03.2019.</td></tr>
<tr><td>7</td><td>Protocols followed for conduction of stability study</td><td colspan="3">Yes</td></tr>
<tr><td>8</td><td>Method used for analysis of FPP</td><td colspan="3">Yes</td></tr>
<tr><td>9</td><td>Drug-excipients compatibility studies (where applicable)</td><td colspan="3">Same excipients used as used by innovator.</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches.</td><td colspan="3">The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th>Batch no.</th><th>Batch Size</th><th>Mfg. Started</th></tr>
<tr><td>TJt-001</td><td>500 vials</td><td>06-2019</td></tr>
<tr><td>TJt-002</td><td>500 vials</td><td>06-2019</td></tr>
<tr><td>TJt-003</td><td>500 vials</td><td>06-2019</td></tr>
</table></td></tr>
<tr><td>11</td><td>Record of comparative dissolution data (where applicable)</td><td colspan="3">Not applicable</td></tr>
<tr><td>12</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Yes</td></tr>
<tr><td>13</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted audit trail reports of stability studies of applied formulation.</td></tr>
<tr><td>14</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td colspan="3">Yes</td></tr>
<tr><td colspan="5">Remarks:
The firm has rectified deficiencies issued vide DRAP letter No. 1-1/2020/PEC DRAP AD PEC XIV dated 19.01.2022.</td></tr>
<tr><td colspan="5">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.</td></tr>
</table>

Deferred Cases

1079.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 28.07.2020 by Government of the People's Republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3567 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	**Ponatinix 15 Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ponatinib Hydrochloride equivalent to Ponatinib…...15mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack of 30's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Iclusig Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Lianyungang Jari Pharmaceutical Co., ltd No. 18 Zhenhua Road, Lianyungang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Background of the case:

Decision in 321st meeting of Registration Board:

Deferred for following points:

i. Justification for conducting Comparative Dissolution studies at "M/s Alpha laboratories India", instead of M/s Beacon Pharmaceuticals Bangladesh.

ii. Regulatory status of Alpha Laboratories India, whether it is licensed entity or otherwise.

In response to the above decision of the Board the firm has submitted the reply on 04.011.2022 which is as under:

The firm has again submitted copy of business agreement dated 04.06.2018 b/w M/s Beacon Pharmaceuticals Bangladesh and M/s Alpha Laboratories India wherein the M/s Alpha Laboratories India shall provide the services being expert in Bioequivalence studies of generic molecules to M/s /s Beacon Pharmaceuticals Bangladesh.

Decision in 323rd meeting of Registration Board:

Deferred for submission of evidence of License/Approval of M/s Alpha Laboratories India, from the

relevant regulatory authority of India.

Remarks in 324th meeting:

The firm has now submitted letter from manufacturer i.e. M/s Beacon Pharmaceuticals Limited indicating a website link of M/s Alpha laboratories India (www.alphalaboratories.in). The website states that **Alpha Laboratories** is a unique and leading Contract Research Organization (CRO) in India with its own in-house laboratory facilities for undertaking **Bioequivalence / Bioavailability Studies, Clinical Trial Studies (Phase I, Phase II, Phase III and Phase IV), Animal Toxicity Study, Dossier and DMF preparation, PSUR (Periodic Safety Update Reports), Medical Writing, Stability Studies, Analytical Method Development and Validation**

Decision in 324th meeting of Registration Board

Deferred for the evidence of approval for conducting Bioequivalence / Bioavailability Studies in name of M/s Alpha Laboratories India from the relevant regulatory authority of India.

Remarks:

The firm has now submitted comparative dissolution studies conducted by the manufacturer with the Innovator Product.

Decision: Registration Board while considering the submitted comparative dissolution studies conducted by the manufacturer i.e. M/s Beacon Pharmaceuticals Limited Bangladesh, Registration Board approved above product with innovator's specifications as per import policy for finished drugs. 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.

1080.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 28.07.2020 by Government of the People's Republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3567 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Ponatinix 45 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ponatinib Hydrochloride equivalent to Ponatinib…...45mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack of 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Iclusig Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Lianyungang Jari Pharmaceutical Co., ltd No. 18 Zhenhua Road, Lianyungang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Background of the case:

Decision in 321st meeting of Registration Board:

Deferred for following points:

iii. Justification for conducting Comparative Dissolution studies at "M/s Alpha laboratories India", instead of M/s Beacon Pharmaceuticals Bangladesh.

iv. Regulatory status of Alpha Laboratories India, whether it is licensed entity or otherwise.

In response to the above decision of the Board the firm has submitted the reply on 04.011.2022 which is as under:

The firm has again submitted copy of business agreement dated 04.06.2018 b/w M/s Beacon Pharmaceuticals Bangladesh and M/s Alpha Laboratories India wherein the M/s Alpha Laboratories India shall provide the services being expert in Bioequivalence studies of generic molecules to M/s /s Beacon Pharmaceuticals Bangladesh.

Decision in 323rd meeting of Registration Board:

Deferred for submission of evidence of License/Approval of M/s Alpha Laboratories India, from the relevant regulatory authority of India.

Remarks in 324th meeting:

The firm has now submitted letter from manufacturer i.e. M/s Beacon Pharmaceuticals Limited indicating a website link of M/s Alpha laboratories India (www.alphalaboratories.in). The website states that **Alpha Laboratories** is a unique and leading Contract Research Organization (CRO) in India with its own in-house laboratory facilities for undertaking **Bioequivalence / Bioavailability Studies, Clinical Trial Studies (Phase I, Phase II, Phase III and Phase IV), Animal Toxicity Study, Dossier and DMF preparation, PSUR (Periodic Safety Update Reports), Medical Writing, Stability Studies, Analytical Method Development and Validation**

Decision in 324th meeting of Registration Board

Deferred for the evidence of approval for conducting Bioequivalence / Bioavailability Studies in name of M/s Alpha Laboratories India from the relevant regulatory authority of India.

Remarks:

The firm has now submitted comparative dissolution studies conducted by the manufacturer with the Innovator Product.

Decision: Registration Board while considering the submitted comparative dissolution studies conducted by the manufacturer i.e. M/s Beacon Pharmaceuticals Limited Bangladesh, Registration Board approved above product with innovator's specifications as per import policy for finished drugs. 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.

1081.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.

	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3298) issued on 01-June-2020 Government of the People's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 4309 dated 08.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Olaparix 50 Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Olaparib INN …..50mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	1x112's in HDPE Bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Lynparza Capsules USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Qingsong Pharmaceutical co., Ltd Suite No. 505 Building No. 2 No. 3377 Kangxin Rd, Pudong New Area Shanghai China 201318
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months
Background of the case: Deferred for clarification/ submission of following documents in 321st meeting of Registration Board		
You have submitted that drug substance is white to off white powder and no polymorphic form exists, however the as per innovator data the Olaparib exists as crystalline powder in four polymorphic forms.		Copy of letter from API manufacturer stating that Polymorphic form of Olaparib is Form-A and is synthesized at their site.
API is characterized by HNMR study only, characterization of the active substance, polymorphic forms/ impurities are required to be performed as per innovator product.		The firm submitted again the HNMR study only.
Particle size (being critical quality attribute) and residual solvents are not specified.		The CoA has been submitted by the manufacturer of API indicating particle size being specified and along with data of residual solvents.
The firm was requested to clarify that drug substance specifications by drug product manufacturer are required (3.2.S.4)) along with results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer used during product developmentand stability studies, along with Certificate of Analysis (CoA).		CoA of the FPP manufacturer is submitted
Comparative dissolution profile is conducted by Alpha Laboratories Mumbai India, as the submitted justification is not relevant.		The firm has submitted copy of agreement between Alpha Laboratories Mumbai India and Beacon Pharmaceuticals Bangladesh. The firm has now submitted letter from manufacturer i.e. M/s Beacon Pharmaceuticals Limited indicating a website link of M/s Alpha laboratories India (www.alphalaboratories.in). The website states that **Alpha Laboratories** is a unique and leading **Contract Research Organization (CRO)** in India with its own in-house laboratory facilities for

	undertaking **Bioequivalence / Bioavailability Studies, Clinical Trial Studies (Phase I, Phase II, Phase III and Phase IV), Animal Toxicity Study, Dossier and DMF preparation, PSUR (Periodic Safety Update Reports), Medical Writing, Stability Studies, Analytical Method Development and Validation**
Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification	The firm has submitted the previous stability data.

Decision in 324th meeting of Registration Board

Deferred for the evidence of approval for conducting Bioequivalence / Bioavailability Studies in name of M/s Alpha Laboratories India from the relevant regulatory authority of India.

Remarks:

The firm has now submitted comparative dissolution studies conducted by the manufacturer with the Innovator Product.

Decision: Registration Board while considering the submitted comparative dissolution studies conducted by the manufacturer i.e. M/s Beacon Pharmaceuticals Limited Bangladesh, Registration Board approved above product with innovator's specifications as per import policy for finished drugs. 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.

1082.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 01-June-2020 Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/5027) issued by M/s Beacon Pharmaceuticals limited.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3566 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 29.09.2020
	The proposed proprietary name / brand name	**Olaparix 150 Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Olaparib INN …..150mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	120's in HDPE Bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Lynparza Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Shanghai Qingsong Pharmaceutical co., Ltd Suite No. 505 Building No. 2 No. 3377 Kangxin Rd, Pudong New Area Shanghai China 201318
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40ºC±2ºC and 75%±5% RH for 6 months. Real time stability studies conducted at 30ºC±2ºC and 65% ± 5% for 24 months
Background of the case: Deferred for clarification/ submission of following documents in 321st meeting of Registration Board		
You have submitted that drug substance is white to off white powder and no polymorphic form exists, however the as per innovator data the Olaparib exists as crystalline powder in four polymorphic forms.		Copy of letter from API manufacturer stating that Polymorphic form of Olaparib is Form-A and is synthesized at their site.
API is characterized by HNMR study only, characterization of the active substance, polymorphic forms/ impurities are required to be performed as per innovator product.		The firm submitted again the HNMR study only.
Particle size (being critical quality attribute) and residual solvents are not specified.		The CoA has been submitted by the manufacturer of API indicating particle size being specified along with data of residual solvents
The firm was requested to clarify that drug substance specifications by drug product manufacturer are required (3.2.S.4)) along with results of analysis of relevant batch(es) of drug substance performed by drug product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA).		CoA of the FPP manufacturer is submitted
Comparative dissolution profile is conducted by Alpha Laboratories Mumbai India, as the submitted justification is not relevant.		The firm has submitted copy of agreement between Alpha Laboratories Mumbai India and Beacon Pharmaceuticals Bangladesh. The firm has now submitted letter from manufacturer i.e. M/s Beacon Pharmaceuticals Limited indicating a website link of M/s Alpha laboratories India (www.alphalaboratories.in). The website states that **Alpha Laboratories** is a unique and leading **Contract Research Organization (CRO)** in India with its own in-house laboratory facilities for undertaking **Bioequivalence / Bioavailability Studies, Clinical Trial Studies (Phase I, Phase II, Phase III and Phase IV), Animal Toxicity Study, Dossier and DMF preparation, PSUR (Periodic Safety Update Reports), Medical Writing, Stability Studies, Analytical Method Development and Validation**
Stability data of Drug Product indicates same test results/ value for the parameters like moisture content, dissolution and assay, hence raw data needs to be submitted for verification		The firm has submitted the previous stability data.
Decision in 324th meeting of Registration Board Deferred for the evidence of approval for conducting Bioequivalence / Bioavailability Studies in name of M/s Alpha Laboratories India from the relevant regulatory authority of India.		

Remarks: The firm has now submitted comparative dissolution studies conducted by the manufacturer with the Innovator Product.		
Decision: Registration Board while considering the submitted comparative dissolution studies conducted by the manufacturer i.e. M/s Beacon Pharmaceuticals Limited Bangladesh, Registration Board approved above product with innovator's specifications as per import policy for finished drugs. 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.		
1083.	**Name and address of Applicant**	**M/s Himmel Pharmaceuticals Pvt. Limited 793-D Block C Faisal Town Lahore Pakistan**
	Product License Holder & Manufacturer	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7363 Dated 20-02-2019
	Fee including differential fee	Rs. 100,000/- Dated 20-02-2019
	Brand Name +Dosage Form + Strength	**Lapanix 250mg Tablet**
	Composition	Each film coated tablet contains: Lapatinib Ditosylate INN 398mg eq. to Lapatinib….250mg
	Finished Product Specification	In-house
	Pharmacological Group	Anti-cancer
	Shelf life	24 Months
	Pack size & Demanded Price	150's & As per SRO
	International availability	Tyverb® 250 mg film-coated tablets (UK)
	Me-too status	TYKERB TABLETS 250MG of M/s Gsk Karachi
	Stability studies	Firm has submitted long term (24 months) at 30+2oC, 65+5%RH & accelerated (06 months) stability data at 40+ 2oC, 75+ 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. DA/6-110/2016/22466 issued on 14-10-2018 by Govt. of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s BEACON Pharmaceuticals Limited. Original product specific letter of authorization from product license holder is submitted.
	Remarks of the Evaluator.	Reference formulation Each film-coated tablet contains lapatinib ditosylate monohydrate, equivalent to 250 mg lapatinib while applied Each film coated tablet contains: Lapatinib Ditosylate INN 398mg eq. to Lapatinib….250mg
	Decision of 293rd meeting: Deferred for revision of composition as per reference product along with submission of requisite fee for the revision. Submission by the firm: The firm has submitted several references from RRAs confirming the monohydrate for of the salt of the applied product that is Lapatinib Ditosylate monhydrtae. Hoever, the API used for manufacturing of the applied product is Lpatinib Ditosylate.	
	Decision of 308th meeting: The Board deferred the case for clarification since the reference product contains Lapatinib Ditosylate Monohydrate while the applied product is manufactured by using Lapatinib Ditosylate. Submission by the firm:	

	The firm has submitted attested copy of declaration from the API manufacturer stating that the API manufacturer had provided the API as Lapatinib Ditosylate to M/s Beacon Pharmaceuticals ltd Bangladesh (the drug product manufacturer).
	Decision of 312th meeting: The Board deferred the case for further deliberation since the API used for manufacturing of reference product is lapatinib ditosylate monohydrate while the applied product is manufactured by using lapatinib ditosylate. Submission by the firm: The firm has submitted that the drug substance used for the manufacturing of the applied product is Lapatinib Ditosylate. A declaration letter from Drug Substance manufacturer is also submitted stating that the drug substance which has been supplied to finished product manufacturer is Lapatinib Ditosylate. It is worthy to bring the fact before the Board that the drug substance falls in BCS Class II (low solubility/high permeability) (Sourse: USFDA Biopharamceutical review of the innovator's product). Decision of 313th meeting: The Board deferred the case for further deliberation since the API used for manufacturing of reference product is lapatinib ditosylate monohydrate while the applied product is manufactured by using lapatinib ditosylate. Submission by the firm: The firm has submitted the General information on drug substance from drug substance manfuactruer that is M/s Qilu AntiBiotic (Linyi) Pharmaceuticals Ltd, China. The firm has stated that the API used in the manufacturing of the applied product is Lapatinib Ditosylate monohydrate as per the structure of the API from DMf.
	Decision of 324th meeting: Deferred for submission of scientific evidence regarding the salt form of the drug substance used in the manufacturing of stability batches since the applicant in previous submission had claimed that they had used "Lapatinib ditosylate" for manufacturing of drug product whereas innovator product is of "Lapatinib ditosylate monohydrate."
Remarks: The firm has now submitted vide dy. No. 6179 dated 06.03.2023 that as per our manufacturer Beacon Pharmaceuticals Limited, they are obtaining API Lapatinib Ditosylate monohydrate from Qilu Antibiotics Pharmaceuticals Co., Ltd. Reference product and applied product both have same API Lapatinib Ditosylate monohydrate. We are submitting following documents for the justification of API; 1. Active substance General information 3.2.S.1 (API Manufacturer Qilu Antibiotics Pharmaceuticals Co., Ltd) 2. Structural formula of API Lapatinib Ditosylate monohydrate 3. Certificate of Analysis of API from API Manufacturer Qilu Antibiotics Pharmaceuticals Co., Ltd 4. Certificate of Analysis of API of M/s Beacon Pharmaceuticals Limited	
Decision: Approved with innovator's specifications as per import policy for finished drugs. 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.	

Miscellaneous Cases

M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore has informed they have withdrawn below applications of drugs for local manufacturing on form-5F (CTD) as these products were also submitted on Form-5D and have been registered. Details are given below:

Sr No.	Brand name	Composition	R&I date	Dy. No
1084.	Dapaglif 5mg Tablet	Each Film Coated Tablet Contains: Dapagliflozin (Propanediol Monohydrate)…5mg	25.01.2022	2372
1085.	Dapaglif 10mg Tablet	Each Film Coated Tablet Contains: Dapagliflozin (Propanediol Monohydrate)…10mg	25.01.2022	2371

1086.	Empaglif Tablets 10mg	Each Film Coated Tablet Contains: Empagliflozin…10mg	15.02.2022	4303

Decision: **Registration Board acknowledged the above information, hence applications of above products submitted by M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore are hereby declared as disposed off being withdrawn by the firm.**

Agenda of ex AD PEC (Mr. Zia Ullah)

Agenda of Evaluator PEC-XVII

Case No.I Registration applications of locally manufactured (Human) drugs on Form 5F.

1087.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 2810 dated 28-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.286415270 dated 13-01-2022.
	The proposed proprietary name / brand name	PRINONE Tablets 267mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet Contains: Pirfenidone……267 mg
	Pharmaceutical form of applied drug	Film-coated red color, oval tablet in alu-alu blister with leaflet pack in unit carton.
	Pharmacotherapeutic Group of (API)	Immuno-suppressants, other immune-suppressants, WHO ATC Code: L04AX05
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 267mg film-coated tablets (USFDA approved)
	For generic drugs (me-too status)	Pirfedow 267mg tablet of M/s Martin Dow Limited. Registration No. 107754
	GMP status of the Finished product manufacturer	GMP certificate issued on 06-07-2020, based on evaluation conducted on 18-06-2020. Tablet Section (General) mentioned GMP certificate.

	Name and address of API manufacturer.	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Pirfenidone:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months at 0, 3rd, 6th, 9th, 12th months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months at 0, 1st, 2nd, 3rd & 6th months. Batches: (OP-PIF-A1-001/20, OP-PIF-A1-002/20, OP-PIF-A1-003/20)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Esbriet 267mg film-coated tablet (Batch No. M100221, Mfg. Date: 03-2021). Summarized test report/results submitted. Comparative dissolution was performed against the same product (Esbriet 267mg film-coated tablet, Batch No. M100221, Mfg. Date: 03-2021) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and water as dissolution time with sampling time points as 05, 10, 15, 20, 30 & 45 minutes. The dissolution profile similarity factor f2 calculated as 92 (acidic buffer pH 1.2), 97 (Acetate buffer pH 4.5), 94 (Phosphate buffer pH 6.8) and 89 (water as dissolution medium).
	Analytical method validation/verification of product	Method validation studies have submitted including introduction, verification of assay method, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
API Lot No.	OP-PIF-A1-002/20
Description of Pack (Container closure system)	A Film coated yellow color, oval tablet in Alu-Alu blister pack in unit carton occupied 21's tablets.
Stability	Real time: 30˚C ± 2˚C / 65% ± 5%RH

Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFL-001	PFL-002	PFL-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	08.10.2021	09.10.2021	09.10.2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: xiii. The HPLC software is 21 CFR compliant. xiv. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. xv. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 22-05-2020, issued by Drug Control Administration, Government of Telangana. Valid for one year from the date of issuance. Firm has also submitted DML copy of API manufacturer which is valid till 09- 09- 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2122OD029/EXP dated 29-04-2021 from Optimus Drug Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India for import of Pirfenidone (Batch No. OP-PIF-A1-002/20, Mfg. Date: 01-07-2020), quantity 08kgs. However, the invoice has not been attested by the concerned AD (I & E). Working standard Batch No. 21 WS0161 (Mfg.Date 26-06-2021), Mfg. date 28-06-2021.
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: (PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5b	Provide valid GMP certificate of API manufacturer as the submitted GMP certificate validity is for one year from the date of issuance that is 22-05-2020.	
2.		Impurities tests of API not performed by the drug product manufacturer.	
3.	2.3.P.2.2.1b	The batch number of Pirfenidone 267mg mentioned in pharmaceutical equivalence studies and that mentioned for comparative dissolution studies and of trial batches manufactured are different.	
4.	3.2.S.4.2	Chromatographic conditions given by API manufacturer has a C8 column, while that mentioned by the Drug product manufacturer as C18 column. Moreover, the run time as recommended by the BP monograph is 4 times that of Pirfenidone, while the run time employed in analysis is about 20 minutes.	
5.		Provide AD (I & E) attested invoice copy for import of Pirfenidone.	
6.		Provide Evidence for import of innovators products (Esbriet 267mg, 534mg & 801mg) for pharmaceutical equivalence and comparative dissolution studies.	
7.		Provide details of available minimum handling capacity for trial batches manufacturing.	
8.		Potency as per CoA of drug product manufacturer is 100.33% (on dried basis), while that given in stability studies calculation/analysis as 99.2.	
9.		API real time stability submitted for 12 months	
10.		Only 03 months stability studies data (both accelerated & real time) have been provided	

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

1088.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of	☒ Domestic sale

	pharmaceutical product	☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 2369 dated 25-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.89888688266 dated 13-01-2022.
	The proposed proprietary name / brand name	PRINONE Tablets 534mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet Contains: Pirfenidone……534 mg
	Pharmaceutical form of applied drug	Film-coated red color, oval tablet in alu-alu blister with leaflet pack in unit carton.
	Pharmacotherapeutic Group of (API)	Immuno-suppressants, other immune-suppressants, WHO ATC Code: L04AX05
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 534mg film-coated tablets (USFDA approved) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP certificate issued on 06-07-2020, based on evaluation conducted on 18-06-2020. Tablet Section (General) mentioned GMP certificate.
	Name and address of API manufacturer.	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Pirfenidone:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months at 0, 3rd, 6th, 9th, 12th months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months at 0, 1st, 2nd, 3rd & 6th months. Batches: (OP-PIF-A1-001/20, OP-PIF-A1-002/20, OP-PIF-A1-003/20)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Esbriet 534mg film-coated tablet (Batch No. M1010321, Mfg. Date: 03-2021). Summarized test report/results submitted. Comparative dissolution was performed against the same product (Esbriet 534mg film-coated tablet, Batch No. M1010321, Mfg. Date: 03-2021) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and water as dissolution medium with sampling time points as 05, 10, 15, 20, 30 & 45 minutes. The dissolution profile similarity factor f2 calculated as 96 (acidic buffer pH 1.2), 95 (Acetate buffer pH 4.5), 92 (Phosphate buffer pH 6.8) and 96 (water as dissolution medium).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.		
API Lot No.	OP-PIF-A1-002/20		
Description of Pack (Container closure system)	A Film coated red color, oval tablet in Alu-Alu blister pack in unit carton occupied 21′s tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFM-001	PFM-002	PFM-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	11.10.2021	12.10.2021	13.10.2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: xvi. The HPLC software is 21 CFR compliant.

		xvii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. xviii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 22-05-2020, issued by Drug Control Administration, Government of Telangana. Valid for one year from the date of issuance. Firm has also submitted DML copy of API manufacturer which is valid till 09- 09- 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2122OD029/EXP dated 29-04-2021 from Optimus Drug Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India for import of Pirfenidone (Batch No. OP-PIF-A1-002/20, Mfg. Date: 01-07-2020), quantity 08kgs. However, the invoice has not been attested by the concerned AD (I & E). Working standard Batch No. 21 WS0161 (Mfg.Date 26-06-2021), Mfg. date 28-06-2021.
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: (PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5b	Provide valid GMP certificate of API manufacturer as the submitted GMP certificate validity is for one year from the date of issuance that is 22-05-2020.	
2.		Impurities tests of API not performed by the drug product manufacturer.	
3.	2.3.P.2.2.1b	The batch number of Pirfenidone 267mg mentioned in pharmaceutical equivalence studies and that mentioned for comparative dissolution studies and of trial batches manufactured are different.	
4.	3.2.S.4.2	Chromatographic conditions given by API manufacturer has a C8 column, while that mentioned by the Drug product manufacturer as C18 column. Moreover, the run time as recommended by the BP monograph is 4 times that of Pirfenidone, while the run time employed in analysis is about 20 minutes.	

5.		Provide AD (I & E) attested invoice copy for import of Pirfenidone.	
6.		Provide Evidence for import of innovators products (Esbriet 267mg, 534mg & 801mg) for pharmaceutical equivalence and comparative dissolution studies.	
7.		Provide details of available minimum handling capacity for trial batches manufacturing.	
8.		Potency as per CoA of drug product manufacturer is 100.33% (on dried basis), while that given in stability studies calculation/analysis as 99.2.	
9.		Only 03 months stability studies data (both accelerated & real time) have been provided	

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

1089.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 2370 dated 25-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.35641913 dated 13-01-2022.
	The proposed proprietary name / brand name	PRINONE Tablets 801mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet Contains: Pirfenidone……801 mg
	Pharmaceutical form of applied drug	Film-coated green color, oval tablet in alu-alu blister with leaflet pack in unit carton.
	Pharmacotherapeutic Group of (API)	Immuno-suppressants, other immune-suppressants, WHO ATC Code: L04AX05
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 801mg film-coated tablets (USFDA approved)

	For generic drugs (me-too status)	Mac-Fenid 801mg tablet of M/s Macter International Limited. Registration No. 105300
	GMP status of the Finished product manufacturer	GMP certificate issued on 06-07-2020, based on evaluation conducted on 18-06-2020. Tablet Section (General) mentioned GMP certificate.
	Name and address of API manufacturer.	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, 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 validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Pirfenidone:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months at 0, 3rd, 6th, 9th, 12th months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months at 0, 1st, 2nd, 3rd & 6th months. Batches: (OP-PIF-A1-001/20, OP-PIF-A1-002/20, OP-PIF-A1-003/20)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Esbriet 801mg film-coated tablet (Batch No. M1020321, Mfg. Date: 03-2021). Summarized test report/results submitted. Comparative dissolution was performed against the same product (Esbriet 801mg film-coated tablet, Batch No. M1020321, Mfg. Date: 03-2021) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and water as dissolution medium with sampling time points as 05, 10, 15, 20, 30 & 45 minutes. The dissolution profile similarity factor f2 calculated as 95 (acidic buffer pH 1.2), 99 (Acetate buffer pH 4.5), 96 (Phosphate buffer pH 6.8) and 91 (water as dissolution medium).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
API Lot No.	OP-PIF-A1-002/20

Description of Pack (Container closure system)	A Film coated green color, oval tablet in alu alu blister pack in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFH-001	PFH-002	PFH-003
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	15.10.2021	16.10.2021	17.10.2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: xix. The HPLC software is 21 CFR compliant. xx. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. xxi. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 22-05-2020, issued by Drug Control Administration, Government of Telangana. Valid for one year from the date of issuance. Firm has also submitted DML copy of API manufacturer which is valid till 09- 09- 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2122OD029/EXP dated 29-04-2021 from Optimus Drug Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India for import of Pirfenidone (Batch No. OP-PIF-A1-002/20, Mfg. Date: 01-07-2020), quantity 08kgs. However, the invoice has not been attested by the concerned AD (I & E). Working standard Batch No. 21 WS0161 (Mfg.Date 26-06-2021), Mfg. date 28-06-2021.
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: (PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5b	Provide valid GMP certificate of API manufacturer as the submitted GMP certificate validity is for one year from the date of issuance that is 22-05-2020.	
2.		Impurities tests of API not performed by the drug product manufacturer.	
3.	2.3.P.2.2.1b	The batch number of Pirfenidone 267mg mentioned in pharmaceutical equivalence studies and that mentioned for comparative dissolution studies and of trial batches manufactured are different.	
4.	3.2.S.4.2	Chromatographic conditions given by API manufacturer has a C8 column, while that mentioned by the Drug product manufacturer as C18 column. Moreover, the run time as recommended by the BP monograph is 4 times that of Pirfenidone, while the run time employed in analysis is about 20 minutes.	
5.		Provide AD (I & E) attested invoice copy for import of Pirfenidone.	
6.		Provide Evidence for import of innovators products (Esbriet 267mg, 534mg & 801mg) for pharmaceutical equivalence and comparative dissolution studies.	
7.		Provide details of available minimum handling capacity for trial batches manufacturing.	
8.		Potency as per CoA of drug product manufacturer is 100.33% (on dried basis), while that given in stability studies calculation/analysis as 99.2.	
9.		Only 03 months stability studies data (both accelerated & real time) have been provided	

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

1090.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP)

		☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 404 dated 05-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.998823005 dated 24-11-2021.
	The proposed proprietary name / brand name	OBETIZON 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	Oral
	Pharmacotherapeutic Group of (API)	Bile and liver therapy, Bile acid preparations.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OCALIVA® Tablet by Intercept Pharmaceuticals, Inc. New York, NY 10001 (US FDA approved with boxed warning as: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS)
	For generic drugs (me-too status)	Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112710
	GMP status of the Finished product manufacturer	GMP certificate issued on 28-03-2022, based on evaluation conducted on 14-10-2021. Tablet Section (General) mentioned in Licensing Division letter for renewal of Drug Manufacturing License.
	Name and address of API manufacturer.	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Obeticholic acid: (Storage conditions 2 -8 ºC.** Stability study conditions: Real time: 5˚C ± 3˚C for 18 months at 0, 3rd, 6th, 9th, 12th, 18th months. Accelerated: 25˚C ± 2˚C / 60% ± 5%RH for 06 months at 0, 1st, 3rd & 6th months. Batches: (KB/OBT/SPP/19/001, KB/OBT/SPP/19/002, KB/OBT/SPP/20/001)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Ocaliva 5mg film-coated tablet (Batch No. A452035, Mfg. Date: 08-2020). Summarized test report/results submitted. Comparative dissolution was performed against the same product Ocaliva 5mg film-coated tablet (Batch No. A452035, Mfg. Date: 08-2020) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and Sod. Phosphate dibasic + Tween 80 (dissolution medium) with sampling time points as 10, 15, 20, 30, 45 & 60 minutes. The dissolution profile similarity factor f2 calculated as 70 (acidic buffer pH 1.2), 77 (Acetate buffer pH 4.5), 75 (Phosphate buffer pH 6.8) and 74 (Sodium Phosphate dibasic + Tween 80, pH 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).		
API Lot No.	KB/OBI/SPP/21/004		
Description of Pack (Container closure system)	A Film coated Light Yellow Colored, round shape, biconvex tablet Which is Plain at both sides.		
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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OBL-001	OBL-002	
Batch Size	5000Tab	5000Tab	
Manufacturing Date	08-2021	08-2021	
Date of Initiation	25-08-2021	26-08-2021	
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported:

<table>
<tr><td></td><td></td><td>xxii. The HPLC software is 21 CFR compliant.
xxiii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available.
xxiv. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>G.M.P Certificate dated 18-11-2019, issued by the State Drugs Controller, Haryana (Food & Drug Administration, Haryana, Panchkula). The certificate is valid till 17-11-2022.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested on 01-07-2021 by AD I&E DRAP, Lahore, has been submitted
<table>
<tr><th>Batch No.</th><th>Invoice No & Date</th><th>Quantity Imported</th><th>Exporter</th></tr>
<tr><td>KB/OBI/SPP/21/004</td><td>KBLEXP/21-22/048 dated 28-05-2021.</td><td>200 GM (1 Box)</td><td>M/s KIMIA BIOSCIENCES LIMITED</td></tr>
</table>
Working standard Batch No. WS-OBI004/21, quantity 2gm.</td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Submitted</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
</table>

Remarks OF Evaluator: **(PEC-XVII)**

Sr. No.	Section	Observation	Reply by the firm
1.		Mobile phase ratio at 3.2.P.5.2 (Drug Product analytical procedure) for assay determination given as Acetonitrile and 0.02% of Formic acid (65:35) and flow rate of 1.3ml/minute while in the "analytical method validation summary report for Obeticholic acid" at 3.2.P.5.3 (Validation of analytical procedure), the Mobile phase mentioned as Acetonitrile: Buffer Solution (35:65), with flow rate as 01 ml/minute. Moreover, the standard solution preparation (0.5mg/ml), quantity of Obeticholic acid WS given as 50mg in 50ml diluent.	
2.		Chromatograms for the analytical method validation of raw material not provided by the drug product manufacturer. The title given as analytical method verification report of	

		Obeticholic acid with specificity and accuracy studies.	
3.		The stability studies data of both trial batches has been submitted in disorder fashion making it difficult to evaluate and understand. It is therefore advised to submit the requisite data in properly arranged form for both trial batches.	
4.		API stability studies data submitted for 18 months.	

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

1091.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 405 dated 05-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.31455909705 dated 24-11-2021.
	The proposed proprietary name / brand name	OBETIZON 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	Oral
	Pharmacotherapeutic Group of (API)	Bile and liver therapy, Bile acid preparations.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OCALIVA® 5mg, 10mg Tablet by Intercept Pharmaceuticals, Inc. New York, NY 10001 (US FDA approved with boxed warning as: HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS)
	For generic drugs (me-too status)	Ocafib 10mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112711
	GMP status of the Finished product manufacturer	GMP certificate issued on 28-03-2022, based on evaluation conducted on 14-10-2021.

		Tablet Section (General) mentioned in Licensing Division letter for renewal of Drug Manufacturing License.
	Name and address of API manufacturer.	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Obeticholic acid: (Storage conditions 2 -8 ºC.** Stability study conditions: Real time: 5˚C ± 3˚C for 18 months at 0, 3rd, 6th, 9th, 12th, 18th months. Accelerated: 25˚C ± 2˚C / 60% ± 5%RH for 06 months at 0, 1st, 3rd & 6th months. Batches: (KB/OBT/SPP/19/001, KB/OBT/SPP/19/002, KB/OBT/SPP/20/001)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Ocaliva 10mg film-coated tablet (Batch No. B482037, Mfg. Date: 09-2020). Summarized test report/results submitted. Comparative dissolution was performed against the same product Ocaliva 10mg film-coated tablet (Batch No. B482037, Mfg. Date: 09-2020) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and Sod. Phosphate dibasic + Tween 80 (dissolution medium) with sampling time points as 10, 15, 20, 30, 45 & 60 minutes. The dissolution profile similarity factor f2 calculated as 80 (acidic buffer pH 1.2), 72 (Acetate buffer pH 4.5), 86 (Phosphate buffer pH 6.8) and 87 (Sodium Phosphate dibasic + Tween 80, pH 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).
API Lot No.	KB/OBI/SPP/21/004
Description of Pack (Container closure system)	A Film coated Light Blue Colored, round shape, biconvex tablet Which is Plain at both sides.

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, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OBH-001	OBH-002	
Batch Size	5000Tab	5000Tab	
Manufacturing Date	08-2021	08-2021	
Date of Initiation	30-08-2021	31-08-2021	
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: xxv. The HPLC software is 21 CFR compliant. xxvi. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. xxvii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 18-11-2019, issued by the State Drugs Controller, Haryana (Food & Drug Administration, Haryana, Panchkula). The certificate is valid till 17-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested on 01-07-2021 by AD I&E DRAP, Lahore, has been submitted **Batch No.** | **Invoice No & Date** | **Quantity Imported** | **Exporter** KB/OBI/SPP/21/004 | KBLEXP/21-22/048 dated 28-05-2021. | 200 GM (1 Box) | M/s KIMIA BIOSCIENCES LIMITED Working standard Batch No. WS-OBI004/21, quantity 2gm.
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	Submitted

	stability chambers (real time and accelerated)	

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.		Mobile phase ratio at 3.2.P.5.2 (Drug Product analytical procedure) for assay determination given as Acetonitrile and 0.02% of Formic acid (65:35) and flow rate of 1.3ml/minute while in the "analytical method validation summary report for Obeticholic acid" at 3.2.P.5.3 (Validation of analytical procedure), the Mobile phase mentioned as Acetonitrile: Buffer Solution (35:65), with flow rate as 01 ml/minute. Moreover, the standard solution preparation (0.5mg/ml), quantity of Obeticholic acid WS given as 50mg in 50ml diluent.	
2.		Chromatograms for the analytical method validation of raw material not provided by the drug product manufacturer. The title given as analytical method verification report of Obeticholic acid with specificity and accuracy studies. Whether validation or verification studies required??	
3.		The firm has submitted two different finished analysis report titled as "Finished analysis report" and "Finished Product Certificate of analysis" for trial batch No. OBH-002 with different assay and dissolution results as 100.73%, 94.15% & 100.93%, 95.08% respectively. Same variation observed in the trial batch No.OBH-001 also. Moreover, chromatograms for sample 1 & sample 2 for assay determination of finished product also not provided.	
4.		Chromatograms for standard runs not provided for trial batch OBH # 001 for accelerated stability data at 3rd month time point.	
5.		Starting dates for stability studies given as 30th & 31st August 2021, while the 3rd month & 6th month stability studies conducted on 21st, 22nd November 2021 & 20th February 2022 that is few days earlier than the scheduled dates.	
6.		Submit audit trial reports for the 6th month time stability studies data	
7.		Submit digital data logger record from 14th November onward till 6th month time point for stability chambers (both accelerated & real time).	
8.		API stability studies data submitted for 18 months.	

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case No.I Registration applications of locally manufactured (Human) drugs on Form 5F (New DML).

M/s Fortune Pharma Private Limited. (New DML)

CLB in its 278th meeting held on 10th and 11th December 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five (05) sections to M/s Fortune Pharma Private Limited

1.	Tablet (General)	2.	Liquid Ampoule (General)
3.	Liquid Syrup (General)	4.	Liquid Vial (General)
5.	Capsule (General)	6.	Tablet (Psychotropic)
7.	Ointment (General) Section	8.	Capsule (Psychotropic)
9.	Sachet (General)	10.	Liquid Ampoule (Psychotropic)

1092.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No 30769 dated 31-10-2022.
	Details of fee submitted	Rs.30,000/- vide challan No. 2890223452 dated 20-07-2022.
	The proposed proprietary name / brand name	VOMITA 4mg/5ml Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml syrup contains: Ondansetron hydrochloride……4mg
	Pharmaceutical form of applied drug	White color round shaped film-coated tablet, packed in Alu-Alu blisters (1×10's) and further packed in printed unit cartons along with a patient information leaflet.
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists, anti-emetics
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	3 × 10's
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	ZOFRAN® (Ondansetron hydrochloride) oral solution, 4mg/5ml (contains 5 mg of ondansetron hydrochloride dihydrate equivalent to 4 mg of ondansetron per 5 mL in amber glass bottles of 50 mL with child-resistant closures) by Novartis pharmaceuticals, Co. (USFDA approved)
	For generic drugs (me-too status)	Xortron Oral Solution (Each 5ml contains: Ondansetron hydrochloride dihydrate eq to ondansetron: 4mg), Registration No. 102367 of M/s McOlson Research Laboratories, Sheikhupura.

	GMP status of the Finished product manufacturer	New DML (DML No. 000924 granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Evidence of section approval.	Liquid syrup (General) Section approval granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.
	Module-II (Quality Overall Summary)	Firm has submitted Quality Overall Summary: Product Dossier details as per WHO QOS-PD template.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Incomplete stability studies summary data sheets of drug substance submitted: Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 06 & 09 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (AOND-17002, AOND-17003 & AOND-17004)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its composition, formulation development, pharmaceutical equivalence, comparative dissolution profile, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zofran 8mg tablet of M/s GSK, Pakistan by performing quality tests such as Identification, Assay, Dissolution and Uniformity of dosage unit. Comparative dissolution profile (CDP) has been performed against the same brand that is Zofran 8mg tablet of M/s GSK, Pakistan in Acid media (pH 1.0-1.2), Acetate Buffer pH 4.5 & Phosphate Buffer (pH 6.8). Discrepancy in data observed. Details given below in remarks column.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.
API Lot No.	AOND-21001
Description of Pack (Container closure system)	1 × 10's in Alu-Alu blisters, packed in a printed carton.

Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-01	T-01
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-01-2022	01-01-2022	01-01-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted M/s Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru, Karnataka, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted Quantity received 1kg as mentioned in CoA of API by drug product manufacturer. Date of received 12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Incomplete submission as raw data sheets, summary data sheets, content uniformity data and dissolution data not provided.
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:

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Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	• The strength/label claim provided is not in accordance with the innovators product that is: Each 5ml syrup contains: Ondansetron (As hydrochloride dihydrate) ……. 4 mg	
2.	1.5.4	• The pack size mentioned as 3×10's	
3.	1.5.10	• The applied dosage form mentioned as: White color round shaped film-coated tablet, packed in Alu-Alu blisters (1×10's) and further packed in printed unit cartons along with a patient information leaflet.	
4.	1.6.5 (b)	• No evidence of approval of manufacturing facility of API by concerned regulatory body submitted.	

5.	2.3	• In introduction part of QOS, the firm has mentioned that Drug product monograph exists in BP and Eu.Ph. However, the same couldn't be confirmed.	
6.	2.3.S.4.4	• The firm has provided HPLC method verification summary instead of Batch analysis data.	
7.	2.3.S..5 (a)	• The firm has submitted CoA of Ondansetron hydrochloride working standard instead of primary reference standard since Ondansetron Hydrochloride official monograph exits in USP.	
8.	3.2.S.4.1	• Specifications for drug substance provided by the drug product manufacturer has two different values for residue on ignition test. Clarification shall be submitted.	
9.	3.2.S.4.2	• Analytical procedure (signed) for the drug substance by the drug product manufacturer shall be submitted.	
10.	3.2.S.7.3	• Incomplete long term stability studies summary data sheets (only for 6 & 9 months) for the drug substance have been submitted by the firm.	
11.	3.2.P.1	• Description & composition of the drug product part is not provided.	
12.	3.2.P.2.1	• The sub-parts, 3.2.P.2.1.1 (Drug substance) & 3.2.P.2.1.2 (Excipients), under components of the drug product are not submitted. Compatibility studies of the Drug Substance(s) with excipients not provided as qualitative composition of the formulation is not similar to innovator / reference product.	
13.	3.2.P.2.2.1	• The API quantity given without considering salt factor of the API. As evident from the trial batches BMR attached at 2.3.R.1, the quantity of API has been dispensed/mentioned without salt factor calculation.	
14.	3.2.P.2.2.1	• In formulation development, the quantity given per bottle (60ml) is 0.04gm, which comes out to be 0.67mg/ml or 3.35mg/5ml while the applied composition is 4mg/5ml.	
15.	3.2.P.2.2.1	• The firm has mentioned that pharmaceutical equivalence conducted against market's comparator product namely Onseron 4mg/5ml oral solution. However, summarized test results of pharmaceutical equivalene submitted is against Zofran 4mg/5ml oral solution.	
16.	3.2.P.2.5	• The microbiological enumeration tests & tests for specified micro-organisms declared as "Not applicable". However, the same are given in USP	

		official monograph of Ondansetron Oral solution as Microbial enumeration tests <61> and Tests for specified Microorganisms <62>.	
17.	3.2.P.3.2	• In batch formula, for 1000 L batch size, the quantity of ondansetron HCl given as 0.4kg and also without considering salt factor calculation. With this quantity, composition/strength of product comes out to be 2mg/5ml of Ondansetron HCl while the applied composition is 4mg/5ml of Ondansetron (as HCl dihydrate).	
18.	3.2.P.4	• No details like specifications, analytical procedures, validation of analytical procedures etc are provided under Control of excipients.	
19.	3.2.P.5.1	• In drug product specifications, the deliverable volume specification mentioned as "In-house". However, the same is given in official monograph (USP) for Ondansetron oral solution under USP general chapter <698> Deliverable volume.	
20.	3.2.P.5.2	• Analytical procedure of drug product not provided by the firm. The firm has submitted extract of USP for Ondansetron Oral solution.	
21.	3.2.P.5.4	• CoA of 03 trial batches submitted in which the assay for trial batch T-03 given as 100.20%, while CoA of same batch has assay result as 101.49%.	
22.	3.2.P.8.1	• In the stability summary and conclusions, the firm has stated that trial batches were kept under real time stability conditions in stability chambers on 01-01-2022 and under accelerated stability conditions on 13-05-2021.	
23.	3.2.P.8.3	• In the stability study data, the Mfg. and Exp. Date of T-02 batch mentioned as 01-2023 and 01-2024 respectively. While stability studies dated provided from 01-01-2022 to 01-06-2022.	
24.	3.2.P.8.3	• Provide raw data sheets, summary data sheets, audit trial reports and digital data logger record for temperature & humidity monitoring of stability chambers (both real and accelerated) in support of stability studies performed of the trial batches.	
25.	3.2.P.8.3	• The wavelength mentioned in chromatogram/HPLC reports submitted is 328nm, however, as per analytical procedures submitted and official monograph of the product, the wave length for assay determination is 216nm.	

26.	3.2.P.8.3	• The time intervals among the chromatograms/HPLC reports of standard and samples analysis, mostly vary from 1-3minutes. While the runtime for each analysis is 15 minutes, with retention time of peaks for all standards and samples as 3.770-3.774 (approx. 3.77). Clarification and scientific justification is required in this regard, as to how such intervals among chromatograms possible, with aforementioned peak retention times and run time of the analysis performed.	
27.	3.2.R.1.1	• The BMR of trial batches (T-01, T-02 & T-03) submitted are blank BMRs, having no details of actual execution of production/manufacturing of the trial batches, such as personnel signatures, in-process checks, reconciliation record, time intervals for different manufacturing steps, quantities dispensed etc.	
28.		Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
29.		Documents for the procurement of API with approval from DRAP (in case of import)	
30.		Compliance record of HPLC software 21CFR & audit trail reports on product testing.	
31.		Record of digital data logger for temperature and humidity monitoring of both stability chambers.	

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case No. III: Registration applications for local manufacturing of (Human) drugs (Differential Fee cases)

1093.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	PRESIN 1mg Injection (IM)
	Composition	Each vial contains: - Lyophilized Terlipressin Acetate…….1mg
	Diary No. Date of R & I & fee	Dy. No. 548 dated 28-05-2011, Rs. 8,000/- dated 28-05-2011 challan dated 26-05-2011 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574077 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Hematinic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) the product is both available as solution for injection and powder for solution for injection.

		Powder and solvent for solution for injection Vial contains white, freeze-dried powder. Ampoule contains solvent. Each vial of powder contains: 1 mg terlipressin acetate equivalent to 0.85 mg terlipressin. 1 ml of reconstituted solution contains 0.2 mg terlipressin acetate.
	Me-too status	Novapressin parenteral injection of M/s Ferozsons laboratories. Registration No. 028416 Terlip lyophilized powder for injection terlipressin (as acetate) ……1mg as lyophilized powder for injection of Getz pharma, Karachi. Reg.No. 066098
	GMP status	Firm has not provided the updated GMP status within last 03 years. However, panel inspection for renewal of DML conducted on 08-03-2019 provided with following recommendation: The panel of inspectors recommends the renewal of DML of M/s Friends Pharma, Lahore bearing No.000531 in respect to its approved sections.
	Remarks of the Evaluator (PEC-XVII)	• Revise the pharmacological group as Posterior pituitary lobe hormones (vasopressin and analogues) (H 01 BA 04) • Revise the label claim as: Each vial contains: - Lyophilized Terlipressin (As Acetate) …….1mg • Provide most recent GMP inspection report conducted within last three years. • In master formulation, average volume per vial mentioned as 1ml. while quantity of Terlipressin acetate given as 5.05mg. please clarify? • Equipment list provided is for Cephalosporin section. • The manufacturing outlines provided do not match the label claim/composition of the applied formulation. • The firm has claimed finished drug product specifications as per USP. However, monograph is not available in USP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Dry powder lyophilized injectable (General) section available as per DML renewal inspection dated 08-03-2019. • Registration Board in its 271st meeting has declared Terlipressin Acetate as biological drug
	Decision: Registration Board rejected the application since the applied formulation is a biological drug and firm does not possess required manufacturing facility of "Lyophilized Injectable vial (Biological) section.	

Registration-I Section

Case No.01. Requirement of Manufacturing Facility for Approved product of M/s Cibex Pvt. Ltd, Karachi

Registration Board in its 277th meeting held on 27th-29th December, 2017 approved the following product in favour of M/s Cibex Pvt. Ltd., Karachi

Name and address of manufacturer / Applicant	M/s Cibex Pvt. Ltd. Factory # 405, SITE, Karachi.
Brand Name +Dosage Form + Strength	Cidrom Gel
Diary No. Date of R& I & fee	Dy No. 658, 5-5-2014, Rs.20000/-
Composition	Each gm contains:

	Cetylpyridinium Chloride……..0.02% Lignocaine……..…0.6% Ethanol……..……33%
Pharmacological Group	Anti-infective, Anti-septic, local anaesthetic
Type of Form	Form-5
Finished Product Specification	Not available
Pack size & Demanded Price	15gm As per PRC
Approval status of product in Reference Regulatory Authorities.	Boots mouth ulcer Gel (EMC)
Me-too status	Somogel by Abbott
GMP status	Last GMP Inspection of Cibex Pvt. Ltd Conducted on 12-2-16 with no conclusive remarks.
Remarks of the Evaluator.	Latest report missing, and the presented report shows availability of 2 sections of oral solid and oral liquid section. Firm also fail to obtain site change approval.
Decision of 269th Meeting	Deferred for submission of latest GMP inspection report conducted within past one year.
Evaluation by PEC	Inspection Date: 16-11-2017 Purpose: GMP Compliance Conclusion: The standard and systems were found to be in compliance with standard GMP regulations.
Decision: Approved with innovator's specifications.	

During processing for issuance of registration letter, it was identified that reference product (i.e., Boots Mouth Ulcer Gel approved by MHRA) contains "Cetylpyridinium Chloride 0.02% + Lignocine base 0.6%". While, alcohol 96% has been included in formulation as an excipient. In this context, the firm has informed that in composition and batch master formula, "Ethanol" was mistakenly mentioned as "active" instead of "excipient". Accordingly, the firm has submitted revised form-5 and master formulation along-with fee of Rs.7500/-(Invoice #41987646836), verified from https://fee.dra.gov.pk/.

Furthermore, it was also observed that the firm has been granted approval of "Ointment (Steroid)" and "Ointment (Non Steroid)" sections (vide Licensing Division's letter dated 04-10-2019), regardless of stating route of administration i.e., "Topical" or "Oral". Accordingly, Licensing Division was requested to opine **whether both the oral and topical gel may be manufactured in the aforementioned facility or otherwise.**

In response, Licensing Division has stated as under:

"Central Licensing Board grants approval of sections with respect to dosage forms of drugs and not on the basis of route of administration and the layout plans for approval are also submitted by the firms on the basis of dosage form and class of drugs to be manufactured. Therefore, the matter regarding registration of drugs with respect to route of administration may be decided by the Registration Board."

Decision: **Registration Board deferred the case on following grounds:**

i. **The applicant will submit protocols for cleaning validation.**
ii. **Expert Committee will be constituted to review the matter regarding manufacturing of oral and topical gel within the same manufacturing facility. Committee will submit its recommendation within 15 days.**
iii. **Data will be compiled for previously issued registrations of oral gels along-with information regarding approved manufacturing facility.**

Case No.2. Request for Change in Registration Status of Products from M/s The Searle Company Limited, F-319, S.I.T.E Karachi to M/s. Searle Pakistan Limited C-14 Manghopir Road, S.I.T.E Karachi.

M/s. Searle Pakistan Limited C-14 Manghopir Road, S.I.T.E Karachi (DML No.000012) has requested for change in registration of below mentioned products from M/s The Searle Company Limited, F-319, S.I.T.E Karachi (DML No.000016) to their name.

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
Copy of registration letter and last renewal status.
Copy of DML of M/s. Searle Pakistan Limited (Formely M/s OBS Pakistan Pvt. Ltd.) C-14 Manghopir Road, S.I.T.E Karachi (Manufacturer) renewed w.e.f on 31-03-2020.

Copy of letter for change of title / management issued by CLB on 23rd November, 2021.
Copy of approved sections by Central Licensing Board of M/s. Searle Pakistan Limited (Formely M/s OBS Pakistan Pvt. Ltd.) C-14 Manghopir Road, S.I.T.E Karachi confirming "Tablet (general)" section.
Copy of GMP certificate M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi on the basis of inspection conducted on 08-10-2021. (Valid till 14th February, 2024) An inspection report dated 21-06-2022 also provided with conclusion that firm is found at good level of GMP compliance.
NOC dated 23-12-2022 issued by M/s The Searle Company Limited, F-319, S.I.T.E, Karachi for transfer of product in the name of M/s. Searle Pakistan Limited C-14 Manghopir Road, S.I.T.E Karachi.
Application with Form-5F and required fee as per relevant SRO.
Relevant undertakings & commitments.

The cases were referred to QMS for scrutinization /evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mst. Urooj Fatima (DD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	028756	Levoxin Tablets 250mg Each tablet contains: Levofloxacin Hemihydrate 256.23mg eq. to Levofloxacin……250mg	Initial Reg. Date in name of M/s Searle Pakistan: **09-09-2002** Registration of drugs to newly approved title i.e. M/s Searle Company Limited, F-319, S.I.T.E Karachi: **15-12-2016** Last renewal applied **on: 30-09-2021** with fee of Rs.15000/-
	Name, address of Applicant / Marketing Authorization Holder		M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **DML # 000012**
	Name, address of Manufacturing site.		M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)**
	Status of the applicant		☒**Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of GMP certificate M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi on the basis of inspection conducted on 08-10-2021. (Valid till 14th February, 2024) An inspection report dated 21-06-2022 also provided with conclusion that firm is found at good level of GMP compliance.
	Evidence of approval of manufacturing facility		Applicant has provided copy of GMP certificate mentioning Tablet (General) section among Formulation sections. Copy of approved sections by Central Licensing Board of M/s. Searle Pakistan Limited (Formely M/s OBS Pakistan Pvt. Ltd.) C-14 Manghopir Road, S.I.T.E Karachi is also provided confirming "Tablet (general)" section.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☒ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission		Dy.No.922 (R&I) dated 10-01-2023
	Details of fee submitted		**For transfer of registration:**

		PKR. 30,000/- DS# 05224793342 dated 19-12-2022
	The proposed proprietary name / brand name	Levoxin Tablets 250mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin Hemihydrate 256.23mg eq. to Levofloxacin……250mg
	Pharmaceutical form of applied drug	White to off-white colored film coated, oval concave shaped tablet plain from one side and scored from other side
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	PKR 406.73/-
	The status in reference regulatory authorities	Levofloxacin 250mg Tablet, Teva Pharma (USFDA)
	For generic drugs (me-too status)	Effiflox 250mg Tablet, Sami Pharmaceuticals (Pvt) Ltd. (Reg#037709)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co., Ltd. Address: No 31, Weisan Road, Zhejiang Hangzhou Bay Shangyu Industrial Area, Shangyu City, Zhejiang Province, P.R.China.
	1.5.11-Proposed Label	Specimen of proposed label (secondary + primary) provided which are in accordance with the Drug (Labelling & Packing) Rules, 1986.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Levofloxacin hemihydrate, related structure, solubilities, and other general properties, manufacturing site, manufacturing process, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, reference standard, container closure and stability studies summaries of Levofloxacin hemihydrate. Similarly, information summaries for drug product (Levoxin) including its description, composition, pharmaceutical development, excipients and their role, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurity profiling of all pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin etc.), specifications based on USP,

<table>
<tr><td></td><td></td><td>analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and stability studies with study protocol.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 48 months. DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Leflox 250mg Tablet of M/s Getz Pharma, Pakistan which shows comparable results within specified limits. The comparative dissolution profile was performed for Levofin 250mg Tablet against the Leflox 250mg Tablet of M/s Getz Pharma, Pakistan. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 10 mins. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Leflox Tab</th><th>Levoxin Tab</th></tr>
<tr><td rowspan="3">i.</td><td rowspan="3">Acidic buffer (pH 1.2)</td><td>5 min</td><td>97%</td><td>98%</td></tr>
<tr><td>10 min</td><td>102%</td><td>101%</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">ii.</td><td rowspan="3">Acetate buffer (pH 4.5)</td><td>5 min</td><td>96%</td><td>87%</td></tr>
<tr><td>10 min</td><td>102%</td><td>101%</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">iii.</td><td rowspan="3">Phosphate Buffer (pH 6.8)</td><td>5 min</td><td>92%</td><td>69%</td></tr>
<tr><td>10 min</td><td>102%</td><td>94%</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided.</td></tr>
</table>

STABILITY STUDY DATA

Manufacturer of API	Shangyu Jingxin Pharmaceutical Co., Ltd. Address: No 31, Weisan Road, Zhejiang Hangzhou Bay Shangyu Industrial Area, Shangyu City, Zhejiang Province, P.R.China.
API Lot No.	DK26-2003191
Description of Pack	ALU/PVC blister of 1x10's in secondary carton

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months) (Continued for 48 months)		
Batch No.	032DT01	032DT02	032DT03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	03-12-2020	03-12-2020	03-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
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 (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Zhejiang Jingxin Pharmaceutical import & export (manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China verified through COA and GMP certificate of manufacturer). Invoice dated 14-05-2020, cleared on 02-06-2020 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

The drug substance for Levoxin 250mg Tablet (Levofloxacin hemihydrate) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China) on USP specifications. The impurity profiling of DS is also carried out for pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin etc). Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 250mg manufactured by M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)** (White to off-white colored film coated, oval concave shaped tablet plain from one side and scored from other side). The method of manufacturing is wet granulation and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in February, 2022, whereas product is manufactured and tested in November, 2020. However, testing was performed as per USP specifications.

M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)** is a GMP complaint unit as per inspection report dated 21-06-2022 with conclusion that firm is found at good level of GMP compliance.

Levoxin 250mg Tablets' pharmaceutical equivalence has been established against the Leflox 250mg Tablet of M/s Getz Pharma, which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Leflox 250mg Tablet of M/s Getz. The clinical particulars and pharmacological properties of the Levofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for acute bacterial sinusitis, uncomplicated cystitis, acute exacerbation of COPD including bronchitis, complicated skin and soft tissue infections / complicated skin and skin structure infections.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.

S.No.	Reg. No.	Registered Brand Name & Composition of Product	Registration Trail
2.	028757	Levoxin Tablets 500mg Each tablet contains: Levofloxacin Hemihydrate 512.46mg eq. to Levofloxacin ……500mg	Initial Reg. Date in name of M/s Searle Pakistan: **09-09-2002** Registration of drugs to newly approved title i.e. M/s Searle Company Limited, F-319, S.I.T.E Karachi: **15-12-2016** Last renewal applied **on: 30-09-2021** with fee of Rs.15000/-
	Name, address of Applicant / Marketing Authorization Holder		M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **DML # 000012**
	Name, address of Manufacturing site.		M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)**
	Status of the applicant		☒**Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of GMP certificate M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi on the basis of inspection conducted on 08-10-2021. (Valid till 14th February, 2024) An inspection report dated 21-06-2022 also provided with conclusion that firm is found at good level of GMP compliance.
	Evidence of approval of manufacturing facility		Applicant has provided copy of GMP certificate mentioning Tablet (General) section among Formulation sections. Copy of approved sections by Central Licensing Board of M/s. Searle Pakistan Limited (Formely M/s OBS Pakistan Pvt. Ltd.) C-14 Manghopir Road, S.I.T.E Karachi is also provided confirming "Tablet (general)" section.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☒ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy.No.923 (R&I) dated 10-01-2023
	Details of fee submitted	**For transfer of registration:** PKR. 30,000/- DS# 07753867897 dated 19-12-2022
	The proposed proprietary name / brand name	Levoxin Tablets 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin Hemihydrate 512.46mg eq. to Levofloxacin ……..... 500mg
	Pharmaceutical form of applied drug	White to off-white colored film coated, oval concave shaped tablet plain from one side and scored from other side
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	PKR 703.96/-
	The status in reference regulatory authorities	Levofloxacin 500mg Tablet, Teva Pharma (USFDA)
	For generic drugs (me-too status)	Leflox 500mg Tablet, Getz Pharmaceuticals (Pvt) Ltd. (Reg#026163)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co., Ltd. Address: No 31, Weisan Road, Zhejiang Hangzhou Bay Shangyu Industrial Area, Shangyu City, Zhejiang Province, P.R.China.
	1.5.11-Proposed Label	Specimen of proposed label (secondary + primary) provided which are in accordance with the Drug (Labelling & Packing) Rules, 1986.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Levofloxacin hemihydrate, related structure, solubilities, and other general properties, manufacturing site, manufacturing process, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, reference standard, container closure and stability studies summaries of Levofloxacin hemihydrate. Similarly, information summaries for drug product (Levoxin) including its description, composition, pharmaceutical development, excipients and their role, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate

<table>
<tr><td></td><td></td><td>of analysis, impurity profiling of all pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin etc.), specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and stability studies with study protocol.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 48 months. DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Leflox 500mg Tablet of M/s Getz Pharma, Pakistan which shows comparable results within specified limits. The comparative dissolution profile was performed for Levofin 500mg Tablet against the Leflox 250mg Tablet of M/Getz Pharma, Pakistan. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 10 mins. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Leflox Tab</th><th>Levoxin Tab</th></tr>
<tr><td rowspan="3">i.</td><td rowspan="3">Acidic buffer (pH 1.2)</td><td>5 min</td><td>69%</td><td>91%</td></tr>
<tr><td>10 min</td><td>99%</td><td>99%</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">ii.</td><td rowspan="3">Acetate buffer (pH 4.5)</td><td>5 min</td><td>37%</td><td>67%</td></tr>
<tr><td>10 min</td><td>91%</td><td>97%</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">iii.</td><td rowspan="3">Phosphate Buffer (pH 6.8)</td><td>5 min</td><td>92%</td><td>69%</td></tr>
<tr><td>10 min</td><td>102%</td><td>94%</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td>Shangyu Jingxin Pharmaceutical Co., Ltd.
Address: No 31, Weisan Road, Zhejiang Hangzhou Bay Shangyu Industrial Area, Shangyu City, Zhejiang Province, P.R.China.</td></tr>
</table>

API Lot No.	DK26-2003191		
Description of Pack (Container closure system)	ALU/PVC blister of 1x10's in secondary carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months) (Continued for 48 months)		
Batch No.	033DT01	033DT01	033DT01
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	03-12-2020	03-12-2020	03-12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
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 (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Zhejiang Jingxin Pharmaceutical import & export (manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China verified through COA and GMP certificate of manufacturer). Invoice dated 14-05-2020, cleared on 02-06-2020 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

The drug substance for Levoxin 500mg Tablet (Levofloxacin hemihydrate) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China) on USP specifications. The impurity profiling of DS is also carried out for pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin etc). Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 500mg manufactured by M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)** (White to off-white colored film coated, oval concave shaped tablet plain from one side and scored from other side). The method of manufacturing is wet granulation and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in February, 2022, whereas product is manufactured and tested in November, 2020. However, testing was performed as per USP specifications.

M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)** is a GMP complaint unit as per inspection report dated 21-06-2022 with conclusion that firm is found at good level of GMP compliance.

Levoxin 500mg Tablets' pharmaceutical equivalence has been established against the Leflox 500mg Tablet of M/s Getz Pharma, which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Leflox 500mg Tablet of M/s Getz. The clinical particulars and pharmacological properties of the Levofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for acute bacterial sinusitis, uncomplicated cystitis, acute exacerbation of COPD including bronchitis, complicated skin and soft tissue infections / complicated skin and skin structure infections.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.

S.No.	Reg. No.	Registered Brand Name & Composition of Product	Registration Trail
3.	039160	Levoxin Tablets 750mg Each tablet contains: Levofloxacin Hemihydrate 768.70mg eq. to Levofloxacin……. 750mg	Initial Reg. Date in name of M/s Searle Pakistan: **16-05-2005** Registration of drugs to newly approved title i.e. M/s Searle Company Limited, F-319, S.I.T.E Karachi: **19-08-2016** Last renewal applied on**:** **30-06-2021** with fee of Rs.15000/-
	Name, address of Applicant / Marketing Authorization Holder		M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **DML # 000012**
	Name, address of Manufacturing site.		M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)**
	Status of the applicant		☒**Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of GMP certificate M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi on the basis of inspection conducted on 08-10-2021. (Valid till 14th February, 2024) An inspection report dated 21-06-2022 also provided with conclusion that firm is found at good level of GMP compliance.
	Evidence of approval of manufacturing facility		Applicant has provided copy of GMP certificate mentioning Tablet (General) section among Formulation sections. Copy of approved sections by Central Licensing Board of M/s. Searle Pakistan Limited (Formely M/s OBS Pakistan Pvt. Ltd.) C-14 Manghopir Road, S.I.T.E Karachi is also provided confirming "Tablet (general)" section.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale

		☒ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No.924 (R&I) dated 10-01-2023
	Details of fee submitted	**For transfer of registration:** PKR. 30,000/- DS# 06551484 dated 19-12-2022
	The proposed proprietary name / brand name	Levoxin Tablets 750mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin Hemihydrate 768.70mg eq. to Levofloxacin……. 750mg
	Pharmaceutical form of applied drug	White to Off-white colored film coated, oblong biconvex shaped tablet plain from one side and scored from other side.
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	PKR 703.96/-
	The status in reference regulatory authorities	Levaquin 750mg Tablet (USFDA)
	For generic drugs (me-too status)	Leflox 750mg Tablet, Getz Pharmaceuticals (Pvt) Ltd. (Reg#047118)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co., Ltd. Address: No 31, Weisan Road, Zhejiang Hangzhou Bay Shangyu Industrial Area, Shangyu City, Zhejiang Province, P.R.China.
	1.5.11-Proposed Label	Specimen of proposed label (secondary + primary) provided which are in accordance with the Drug (Labelling & Packing) Rules, 1986.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Levofloxacin hemihydrate, related structure, solubilities, and other general properties, manufacturing site, manufacturing process, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, reference standard, container closure and stability studies summaries of Levofloxacin hemihydrate. Similarly, information summaries for drug product (Levoxin) including its description, composition, pharmaceutical development, excipients and their role, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications,

<table>
<tr><td></td><td></td><td>analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurity profiling of all pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin etc.), specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and stability studies with study protocol.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 48 months. DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Leflox 750mg Tablet of M/s Getz Pharma, Pakistan which shows comparable results within specified limits. The comparative dissolution profile was performed for Levofin 250mg Tablet against the Leflox 750mg Tablet of M/Getz Pharma, Pakistan. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 10 mins. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Leflox Tab</th><th>Levoxin Tab</th></tr>
<tr><td rowspan="4">i.</td><td rowspan="4">Acidic buffer (pH 1.2)</td><td>5 min</td><td>105%</td><td>97%</td></tr>
<tr><td>10 min</td><td>107%</td><td>105%</td></tr>
<tr><td>15 min</td><td>109%</td><td>108%</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">ii.</td><td rowspan="3">Acetate buffer (pH 4.5)</td><td>5 min</td><td>104%</td><td>85%</td></tr>
<tr><td>10 min</td><td>106%</td><td>99%</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">iii.</td><td rowspan="3">Phosphate Buffer (pH 6.8)</td><td>5 min</td><td>103%</td><td>66%</td></tr>
<tr><td>10 min</td><td>105%</td><td>97%</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
</table>

Manufacturer of API	Shangyu Jingxin Pharmaceutical Co., Ltd. Address: No 31, Weisan Road, Zhejiang Hangzhou Bay Shangyu Industrial Area, Shangyu City, Zhejiang Province, P.R.China.		
API Lot No.	DK26-2003191		
Description of Pack (Container closure system)	ALU/PVC blister of 1x10's in secondary carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months) (Continued for 48 months)		
Batch No.	071DT01	071DT02	071DT03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	30-08-2021	30-08-2021	30-08-2021
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 (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Zhejiang Jingxin Pharmaceutical import & export (manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China verified through COA and GMP certificate of manufacturer). Invoice dated 14-05-2020, cleared on 02-06-2020 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

The drug substance for Levoxin 750mg Tablet (Levofloxacin hemihydrate) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China) on USP specifications. The impurity profiling of DS is also carried out for pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin etc). Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 750mg manufactured by M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)** (White to off-white colored film coated,

oblong biconvex shaped tablet plain from one side and scored from other side). The method of manufacturing is wet granulation and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in February, 2022, whereas product is manufactured and tested in July / August, 2021. However, testing was performed as per USP specifications.

M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi-75700, Pakistan **(DML # 000012)** is a GMP complaint unit as per inspection report dated 21-06-2022 with conclusion that firm is found at good level of GMP compliance.

Levoxin 750mg Tablets' pharmaceutical equivalence has been established against the Leflox 750mg Tablet of M/s Getz Pharma, which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Leflox 750mg Tablet of M/s Getz. The clinical particulars and pharmacological properties of the Levofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for acute bacterial sinusitis, uncomplicated cystitis, acute exacerbation of COPD including bronchitis, complicated skin and soft tissue infections / complicated skin and skin structure infections.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.

Decision: Registration Board decided as under:

i. **Cancelled registration of following products from the name of M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016) subject to submission of request for withdrawal/ cancellation of registration of below mentioned products:**

S. No.	Reg. No.	Product Name & Composition
1.	028756	Levoxin Tablets 250mg Each tablet contains: Levofloxacin Hemihydrate 256.23mg eq. to Levofloxacin……250mg
2.	028757	Levoxin Tablets 500mg Each tablet contains: Levofloxacin Hemihydrate 512.46mg eq. to Levofloxacin ……500mg
3.	039160	Levoxin Tablets 750mg Each tablet contains: Levofloxacin Hemihydrate 768.70mg eq. to Levofloxacin……. 750mg

ii. **Approved registration of following products in the name of M/s Searle Pakistan Limited (Formerly M/s OBS Pakistan Pvt. Ltd.) C-14, S.I.T.E, Karachi (DML No.000012) on the basis of NOC submitted by M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016).**
   a. **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
   b. **Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.**

S. No.	Product Name & Composition
i.	Levoxin Tablets 250mg Each film coated tablet contains:

	Levofloxacin Hemihydrate 256.23mg eq. to Levofloxacin……250mg (USP Specifications)
ii.	**Levoxin Tablets 500mg** **Each film coated tablet contains:** **Levofloxacin Hemihydrate 512.46mg eq. to Levofloxacin ……. 500mg (USP Specifications)**
iii.	**Levoxin Tablets 750mg** **Each film coated tablet contains:** **Levofloxacin Hemihydrate 768.70mg eq. to Levofloxacin……. 750mg (USP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.3. Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Ltd, Karachi to M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) by way of Contract Manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348).

M/s. AGP Limited, D-109, S.I.T.E, Karachi has requested to change the registration status of following products from M/s Novartis Pharma (Pakistan) Ltd., 15-West Wharf, Dockyard Road, Karachi to M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) with permission for contract manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348). **The products were registered in finished import as per following detail:**

S/N	Reg. No.	Name & Composition	Finished Import from	
1.	084165	Zofran 8mg/4ml Injection Each 4ml contains: Ondansetron HCl Dihydrate……..…8mg (USP Specifications)	**Product License Holder:-** M/s. Novartis Pharma Schweiz AG 6343 Risch Switzerland **Manufacturer:-** M/s Sandoz Manufacturing Inc. 145 Jules Leger, Boucherville Quebec QC J4B 7KT, Canada	Initial Reg. Date: **07-04-2017** Change of Manufacturing Site: **03-11-2021** Last Renewal Submission Date: **18-03-2022 with fee of Rs.30000/-**
2.	084164	Zofran 8mg Tablet Each film coated tablet contains Ondansetron HCl Dihydrate…….8mg	**Product License Holder:-** M/s. Novartis Pharma Schweiz AG 6343 Risch Switzerland **Manufacturer:-** M/s Aspen Bad Oldesloe GmbH Industriestrasse 32-36, 23843 Bad Oldesloe, Deutshland	Initial Reg. Date: **07-04-2017** Last Renewal Submission Date: **18-03-2022 with fee of Rs.30000/-**

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of DML of M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348) w.e.f. 06-02-2020.
ii. Copy of approval letter (dated 30-06-2020) issued by Licensing Division for renewal of DML of M/s AGP Limited, B-23-C, S.I.T.E, Karachi, confirming "Tablet (general)" and "Liquid Ampoule (General)" sections.
iii. Copy of last GMP Inspection report dated 06-07-2022 concluding good level of GMP compliance by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)
iv. NOC from M/s. Novartis Pharma Pakistan, 15-West Wharf, Dockyard Road, Karachi for transfer of registration to M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) issued on 10-03-2023.
v. Agreement of Contract manufacturing among M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) and M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348).
vi. Relevant undertakings & commitments.

The cases were referred to QMS for evaluation. Detail of submitted documents and remarks of evaluator have been mentioned as under:

Evaluator: Mr. Abdul Mughees Mudassir (AD to CEO)

1.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited D-109, S.I.T.E., Karachi-75700, Pakistan.
	Name, address of Manufacturing site.	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35007 dated 02/12/2022
	Details of fee submitted	Fee Slip Number: 669162174, PKR 75,000/-: dated 21/11/2022
	The proposed proprietary name / brand name	Zofran 8mg/4ml injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule contains: Ondansetron (as Ondansetron hydrochloride dihydrate) ….8mg
	Pharmaceutical form of applied drug	Injection (Intravenous)
	Pharmacotherapeutic Group of (API)	Antiemetic, Serotonin (5-HT3) antagonists
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	4ml x 5's & 4ml x 8's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Zofran Injection 2mg/ml by GSK S.p.A, Italy.
	For generic drugs (me-too status)	Emesson 2mg/ml Injection by M/s Highnoon Laboratories Ltd. Reg. No. 110635
	GMP status of the Finished product manufacturer	GMP certificate granted on 17/06/2021
	Name and address of API manufacturer.	CTX Lifesciences Pvt. Ltd. Address: Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat – 394 230, Gujarat, INDIA Phone: +91 261-2399669 +91 261-2398456 Fax: +91 261-2398547
	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 Ondansetron 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 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: Accelerated: 40°C ± 2°C, 75%RH ± 5% Long-term: 30°C ± 2°C, 75%RH ± 5% Batches: ON130001, ON130002 and ON130003
	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 has been established against the reference product.
	Analytical method validation/verification of product	Method Validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat – 394 230, Gujarat, INDIA		
API Lot No.	21ON000047		
Description of Pack (Container closure system)	Pack size: 4ml x 5's & 4ml x 8's Clear colorless solution free from foreign particles filled in 5ml clear glass ampoule type (I), packed in a printed unit carton		
Stability Storage Condition	Accelerated stability study: 40°C ± 2°C / 75 ± 5% RH Long-term stability study: 30°C ± 2°C / 65 ± 5% RH		
Time Period	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3 & 6 months		
Frequency	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Batch No.	22/036-STB/OND-INJ/01	22/037-STB/OND-INJ/02,	22/038-STB/OND-INJ/03
Batch Size	500 Ampoules	500 Ampoules	500 Ampoules
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	16-03-2022	16-03-2022	16-03-2022
No. of Batches	03		

Administrative Portion

7.	Reference of previous approval of applications with stability study data of the firm (if any)	-
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22063346 issued by Food & Drugs Control Administration valid till 29/05//2025.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

- Compatibility of the FPP with normal saline under 2.3.P.2.6 has not been submitted.

Response of Firm:

- The firm has submitted compatibility studies with diluents including normal saline.

2.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited D-109, S.I.T.E., Karachi-75700, Pakistan.
	Name, address of Manufacturing site.	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35006 dated 02/12/2022
	Details of fee submitted	Fee slip number: 1793559901, PKR 75,000/-: dated 21/11/2022
	The proposed proprietary name / brand name	Zofran 8mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron (as Ondansetron hydrochloride dihydrate) ….8mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antiemetic, Serotonin (5-HT3) antagonists
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1x10’s
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Sandoz Ondansetron 8mg Tablet by Sandoz Canada Inc.

	For generic drugs (me-too status)	Ongene 8mg Tablet by M/s High-Q Pharmaceuticals Reg. No. 081451
	GMP status of the Finished product manufacturer	GMP certificate granted on 17/06/2021
	Name and address of API manufacturer.	CTX Lifesciences Pvt. Ltd. Address: Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat – 394 230, Gujarat, INDIA Phone: +91 261-2399669 +91 261-2398456 Fax: +91 261-2398547
	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 Ondansetron 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 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: Accelerated: 40°C ± 2°C, 75%RH ± 5% Long-term: 30°C ± 2°C, 75%RH ± 5% Batches: ON130001, ON130002 and ON130003
	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 reference product that is Zofran 8mg Tablet by Aspin Bad Oldesloe., Germany CDP has been performed against the same brand that is Zofran 8mg Tablet by Aspin Bad Oldesloe., Germany in pH 1.2, pH 4.5 & pH 6.8 released more than 85 % within 15minutes and comparative profile is similar.
	Analytical method validation/verification of product	Method Validation studies have submitted.
STABILITY STUDY DATA		

Manufacturer of API	CTX Lifesciences Pvt. Ltd. Block No. 251-252 Sachin- Magdalla Road, GIDC, Sachin, Surat – 394 230, Gujarat, INDIA		
API Lot No.	21ON000047		
Description of Pack (Container closure system)	Pack size: 1 x 10's Alu/Alu blister, packed in a secondary carton with a leaflet inside		
Stability Storage Condition	Accelerated stability study: 40°C ± 2°C / 75 ± 5% RH Long-term stability study: 30°C ± 2°C / 65 ± 5% RH		
Time Period	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3 & 6 months		
Frequency	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Batch No.	22/042-STB/OND-TAB/01	22/046-STB/OND-TAB/02,	22/047-STB/OND-TAB/03
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	28-03-2022	28-03-2022	28-03-2022
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 GMP certificate No. 22063346 issued by Food & Drugs Control Administration valid till 29/05//2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Registration Board decided as under:

i. **Cancelled the registration of Zofran 8mg/4ml Injection (Reg. No. 084165) and Zofran 8mg Tablet (Reg. No.084164) subject to submission application of withdrawal/ cancellation of registration of Zofran 8mg/4ml Injection (Reg. No. 084165) and Zofran 8mg Tablet (Reg. No.084164) by the M/s Novartis Pharma (Pakistan) Ltd., 15-West Wharf, Dockyard Road, Karachi, though the NOC has been submitted by the M/s Novartis Pharma (Pakistan) Ltd., 15-West Wharf, Dockyard Road, Karachi.**

ii. **Approved registration of Zofran 8mg/4ml Injection and Zofran 8mg Tablet in the name of M/s AGP Limited, D-109, S.I.T.E., Karachi-75700, Pakistan on the basis of NOC submitted by the M/s Novartis Pharma (Pakistan) Ltd., 15-West Wharf, Dockyard Road, Karachi**

Case No. 04: Deferred Products of M/s Onyx Pharmaceuticals, Mansehra.

Registration Board in its 234th meeting (held on 23rd and 24th July, 2012) deferred the following products of M/s Onyx Pharmaceuticals, Plot No.30-A, Small Industrial Estate, Manshera as per details mentioned vide column II & III of below table. The firm has now requested for issuance of registration & submitted requisite fee along-with required documents/ information as per detail recorded vide Column IV of below table:

S/ N	Product Name & Composition	Decision of RB-234	Current Status/ Documents Submitted by the Firm	RRA & Generic Status/ Remarks
I	II	III	IV	V
1.	Artilume Tablets Each tablet contains:- Artemether……...20mg Lumefantrine….120mg (Antimalarial) **Demanded MRP/ Pack Size** As per SRO/16's	Deferred as per policy of 5 products per section for new license/new section (product is recommended by the me-too committee)	• Dy.No.33883/R&I dated 24-11-2022. • Photocopies of previous submissions as evidence for submission of fee of Rs.8000/- and Rs.12000/- • Fee of Rs.7500/- (S#434294756989, verified from https://fee.dra.gov.pk/) for issuance of IP Specifications (Dy.No.6620/R&I dated 08-03-2023)	• WHO Pre-qualified product.
2.	Levocit Tablets Each tablet contains:- Levocetirizine (as Dihydrate)……2.5mg (H1 Blockers) **Demanded MRP/ Pack Size** As per SRO/10's	Deferred as per policy of 5 products per section for new license/new section (product is recommended by the me-too committee)	• Dy.No.33882/R&I dated 24-11-2022 • Revised pack size of 1x10's • & 2x10's • Photocopies of previous submissions as evidence for submission of fee of Rs.8000/- and Rs.12000/- • Fee of Rs.30000/- (S#42435283227, verified from https://fee.dra.gov.pk/) for correction in strength, composition/ label claim and FPP Specifications as per following details: *"Levocit Tablets* *Each film coated tablet contains:-* *Levocetirizine Dihydrochloride…….5mg* *(USP Specifications)"* (Dy.No.6620/R&I dated 08-03-2023)	• USFDA approved • Zeocit Tablet of M/s Glitz, Islamabad
3.	Kanclar 250mg Tablets Each tablet contains:- Clarithromycin…… …250mg (Macrolide) **Demanded MRP/ Pack Size** As per SRO/10's	Deferred as per policy of 5 products per section for new license/new section (product is recommended by the me-too committee)	• Dy.No.33884/R&I dated 24-11-2022 • Photocopies of previous submissions as evidence for submission of fee of Rs.8000/- and Rs.12000/- • Fee of Rs.7500/- (S#2894114976, verified from https://fee.dra.gov.pk/) for correction in label claim and FPP Specifications as per following details:	• USFDA approved • Larith Tablet of M/s Genix, Karachi

			"Kanclar 250mg Tablets *Each film coated tablet contains:-* *Clarithromycin……250mg* *(USP Specifications)"* (Dy.No.6620/R&I dated 08-03-2023)	
4.	Kanclar 500mg Tablets Each tablet contains:- Clarithromycin……..500mg (Macrolide) **Demanded MRP/ Pack Size** As per SRO/10's	Deferred as per policy of 5 products per section for new license/new section (product is recommended by the me	• Dy.No.33885/R&I dated 24-11-2022. • Photocopies of previous submissions as evidence for submission of fee of Rs.8000/- and Rs.12000/- • Fee of Rs.7500/- (S#68811868, verified from https://fee.dra.gov.pk/) for correction in label claim and FPP Specifications as per following details: *"Kanclar 500mg Tablets* *Each film coated tablet contains:-* *Clarithromycin……500mg* *(USP Specifications)"* (Dy.No.6620/R&I dated 08-03-2023)	• USFDA approved • Larith Tablet of M/s Genix, Karachi
5.	Levonyx 250mg Tablets Each tablet contains:- Levofloxacin hemihydrate eq.to Levofloxacin…250mg (Quinolone) **Demanded MRP/ Pack Size** As per SRO/10's	Deferred as per policy of 5 products per section for new license/new section (product is recommended by the me-too committee)	• Dy.No.33881/R&I dated 24-11-2022 • Photocopies of previous submissions as evidence for submission of fee of Rs.8000/- and Rs.12000/- • Fee of Rs.7500/- for correction in label claim and FPP Specifications as per following details: *"Each film coated tablet contains:-* *Levofloxacin Hemihydrate eq.to Levofloxacin……250mg* *(USP Specifications)"* (Dy.No.6620/R&I dated 08-03-2023)	• USFDA Approved • Warrior Tablet of M/s Nabiqasim, Karachi.
• Copy of last GMP Inspection report dated 01-07-2021 with following conclusion: ***"After detailed inspection meeting was held with the firm management Mr. Furqan along-with their technical staff. The firm has shown its willingness for improving their facility and made commitment to improve facility in line with the GMP requirements with minimum possible time."*** • Copy of DML (No. 000440) dated 15.06.2011 along-with application submitted for renewal of DML • Copy of panel inspection report for renewal of DML (dated 15-03-2011), confirming "Tablet (General/ Antibiotics) Section"				

Decision: **Registration Board noted that the last GMP Inspection of the applicant which was conducted on 01-07-2021 (i.e., almost 2 years ago) is not conclusive regarding GMP status (whether 'Compliant' or 'Non-Compliant'). Accordingly, the Board decided to refer the last GMP inspection report of M/s Onyx Pharmaceuticals, Plot No.30-A, Small Industrial Estate, Manshera to QA&LT Division, DRAP for seeking opinion/ comments regarding current GMP status of the firm.**

Case No.01: Registration of Glutathion 600mg Injection

Registration Board in its 323rd meeting while considering the case of TAD 600mg dry powder injection (Glutathione 600mg Injection) of M/s 2 World Traders Pakistan. 55/2, Main Khayaban-e-Hafiz, DHA, Karachi, Pakistan decided as under:

Proceedings & Decision of 323rd meeting: The Board was apprised that in 291st meeting application of M/s Friends Pharma, Lahore was approved on basis of international reference of AIFA of Italy. The application was submitted on Form 5D, whereas the firm didn't submit product development and stability studies data as required by the Board for such applications. Moreover, reference was also forwarded to the pricing division for MRP fixation. The Board deliberated the matter in detail and decided as follows:

- **To refer the case to "Society of Oncology, Pakistan" for expert opinion regarding therapeutic use and need of applied formulation.**
- **To advise M/s Friends Pharma, Lahore to submit the stability studies data as per checklist approved by Board in its 293rd meeting and case will be considered by the Board after above opinion.**

In response of above decision of the Board, M/s. Friends Pharma has replied that application for registration of Tationil-600 Injection (Lyophilized Glutathione) was submitted on Form-5D (for new molecules) but later on they had submitted stability data of 6 months for both accelerated and real time, as mentioned in minutes of 265th meeting the Registration Board. Extract of case presented in 265th meeting along with decision of the Board is as under:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
1.	**M/s. Friends Pharma (Pvt.) Limited.** 31-Km, Ferozepur Road, Lahore.	Tationil-600 Injection Each Vial contains:- Lyophilized Glutathione (B.P)…600mg Antioxidant	Form 5-D Dy. No. 424 11-08-2014 Rs.20,000/- Rs. 30,000/- 29.01.15 As per SRO Not confirmed.	Not confirmed Form 5-D Panel got impression that the Operations at the factory premises were compliant to GMP and guidelines. (21-05-2014) However it has been stated about Lyophilized section that the dedicated section was found ready for inspection.	1. Deferred in **248th** Meeting. Final notice for 30 days for rectification of below mentioned shortcomings/ observations. a. An undertaking/commitment regarding Label claims and prescribing information being same as approved by reference drug agencies e.g., FDA, TGA, MHLW, EMA and Health Canada is required. b. International availability of

					formulation in reference Stringent Regulatory Agencies not confirmed. c. Evidence and verification of lyophilizer by area FID that the said instruments is in functional condition are required. d. Lab scale stability studies e. Undertaking that in case of resemblance of brand name and packaging of applied product, the firm will change these; is required.

STABILITY STUDY DATA

Drug	Tationil-600 Injection (Lyophilized Glutathione)		
Name of Manufacturer	M/s. Friends Pharma (Pvt.) Limited, Lahore.		
Manufacturer of API			
API Lot No.	**B150720**		
Description of Pack (Container closure system)	Sterile lyophilized powder in vials.		
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 26 Weeks Accelerated: 26 Weeks		
Frequency	Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 (Week) Accelerated: 0,1,2,3,4,6,8,12,16,20,24,26 (Week)		
Batch No.	**TL001**	**TL002**	**TL003**
Batch Size	2,500 Vials	2,500 Vials	2,500 Vials
Manufacturing Date	November 2015	November 2015	November 2015
Date of Initiation	November 2015	November 2015	November 2015
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	**No**
2.	Approval of API by regulatory authority of country of origin	**No**

	or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	
3.	Protocols followed for conduction of stability study and details of tests.	**No**
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**No**
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	**No**
8.	Commitment to follow Drug Specification Rules, 1978.	**No**

REMARKS OF EVALUATOR
(AD PEC-I)

Firm has claimed Manufacturer Specification

- Firm has provided 06 Months accelerated and Real Time Stability Study Data.
- Aforementioned documents as required in 251st DRB Meeting are missing.
- Documents as required from the firm in 248th DRB meeting are missing except 'd. stability study data'.

Decision: Deferred for evidence of approval of applied formulation by reference regulatory authorities & shortcomings stated above

As per minutes of 265th meeting of the Board that firm has submitted stability data of 26 Week of real time and accelerated and case was deferred due to approval status of product in reference regulatory authorities. Formulation is approved in Italy and Registration Board in its 291st meeting approved the product and registration letter is pending due to fixation of MRP.

Decision: Registration Board deferred the case for submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. Moreover, Board decided to refer the case to "Society of Oncology, Pakistan" for expert opinion regarding therapeutic use and need of applied formulation.

Case No. 02: Correction in Minutes of registration Board.

i. M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.

Registration Board in its 322nd meeting approved following registration application of M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore. Detail is as under:

Name and address of manufacturer/ Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
Brand Name + Dosage Form + Strength	Irosak tablet 150mg
Composition	Each film-coated tablet contains: Elemental iron as iron polymaltose complex ….150mg
Diary No. Date of R & I & fee	Dy.No.17064; 04-10-2017; Rs.20,000/- (04-10-2017)
Pharmacological Group	Anti- Anemic.
Type of Form	Form-5
Finished product Specification	Manufacturers
Pack size & Demanded Price	2x 10's & s per SRO
Approval status of product in Reference Regulatory Authorities	Not applicable
Me-too status	Could not be confirmed in the applied formulation as 100mg is available.
GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational mode. At the time of inspection unit was found non-operational."
Remarks of the Evaluator	The evidence of applied strength of me-too status could not be verified.

	GMP status could not be confirmed by the report.
Previous decision	Deferred in 290th DRB meeting for evidence of applied formulation/ drug already approved by DRAP (generic /me-too status) along with registration number, brand name and name of firm. Further, Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.
Evaluation by PEC- XIII	Firm has submitted wrong me- too status as Ferricure Capsule of M/s S.J. & G Fazul Ellahie, Karachi 050637 while tablets are applied. Firm has submitted its latest GMP inspection report which was conducted on 03-02-2020 and the report concludes satisfactory level of GMP compliance.
Decision of 296th meeting.	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me too status) along with registration number, brand name and name of firm.
Submission of the firm:	Firm has submitted their reply wherein they have requested to change their formulation of IROSAK tablet 150mg (Iron polysaccharide complex) from tablets to capsules and submitted fee of 5000/- vide deposit slip No. 1910045 dated 31-12-2020.
Evaluation by PEC- XIII	For change of formulation, requisite fee is 30,000/-.
Decision of 307th meeting.	Deferred for submission of fee applicable to the change of formulation.
Reply by the firm.	Firm has submitted a differential fee of 25000/- vide slip No. 2045102990 dated 27-09-2022.
Evaluation by PEC- XIII	**Revised formulation is as under;** **Each capsule contains:** **Elemental iron as iron polymaltose complex.…150mg** • Capsule (General) section approved vide letter No. F. 6-3/2014-Lic (M-234) dated 04-04-2014. • Copy of GMP certificate No. 114/2020-DRAP (AD-1910741-175) dated 22-07-2020 issued on the basis of inspection conducted on 03-02-2020 is submitted.
Decision: Approved with innovator's specifications. Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

Firm has submitted that their original registration application was for Iron Polysaccharide complex while DRAP inadvertently considered it as an application for Iron Polymaltose complex. They have further submitted they had applied for change of formulation form Iron Polysaccharide Tablet to Capsule.

As evident from above agenda at point "Submission of the firm" and receiving of the application along with other correspondence, stance of the frim is justified that firm has applied form registration of Iron Polysaccharide Complex 150mg Capsule instead of Iron Polymaltose 150mg Capsule. Accordingly, correct formulation is as under:

"Each capsule contains:
Elemental iron as iron polysaccharide complex.…150mg"

Mee-too status: Irotit 150mg Capsules Reg. No. 110607 (M/s. Titlis Pharma)

Decision: **Registration Board decided to approve the correction in above product with following details.**

"Each capsule contains:
Elemental iron as iron polysaccharide complex.…150mg"

- **Registration letter will be issued after submission of fee of Rs. 7500/- for correction/pre-approval change in the method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

ii. M/s. Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.

Registration Board in its 323rd meeting approved following registration application of M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore. Detail is under:

Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
Brand Name + Dosage Form + Strength	VISKO PLUS Cream

Composition	Each gram contains: Fluocinolone acetonide……0.25mg Hydroquinone……..40mg Tretinoin…….…….0.05mg
Diary No. Date of R & I & fee	Dy. No. 1247 dated 11-01-2011, Rs. 8,000/- Challan dated 14-12-2010 (Photocopy), Dy. No. 25870 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955348 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
Pharmacological Group	Anti-inflammatory and antipruritic drugs
Type of Form	Form 5
Finished product Specification	Manufacturer Specifications
Pack size & Demanded Price	15gm, 30gm, As per SRO
Approval status of product in Reference Regulatory Authorities	TRI-LUMA® (fluocinolone acetonide, hydroquinone, and tretinoin) cream, 0.01%/4%/0.05%. Each gram of TRI-LUMA Cream contains 0.1mg of fluocinolone acetonide, 40 mg of hydroquinone, and 0.5 mg of tretinoin. (US FDA approved)
Me-too status	Troika Cream (Hydroquinone: 40mg (4% w/w); Tretinoin: 0.5mg (0.05% w/w); Fluocinolone acetonide: 0.1mg (0.01% w/w) of M/s ARP (Pvt) Ltd. National Industrial Zone, Rawat Islamabad. Registration No. 099219
GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
Remarks of the Evaluator (PEC-XVII)	• Ointment/cream Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Firm revised label claim as per reference productd as: Each gram contains: Fluocinolone acetonide……0.01% Hydroquinone…….4% Tretinoin…….0.5%, but has not submitted the requisite fee. • The product is non-pharmacopoeial. • As per panel inspection for renewal of DML, "Three dispensing areas were developed where dispensing hoods were installed, on each for dispensing of general, psychotropic and steroidal materials". • Firm has provided undertaken that the product (Visko plus cream) has never been discussed or deferred in any meeting and that given information are true.
Decision: Approved with Innovator's specifications & revised label claim as: **Each gram contains:** **Fluocinolone acetonide……0.01%** **Hydroquinone……..4%** **Tretinoin……..0.5%.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of Fluocinolone acetonide quantitiy from 0.25mg/gm to 0.01% in line with reference product), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	

While processing registration letter it was transpired that in USFDA approved reference product, strength of Tretinoin is 0.05% instead of 0.5%. firm has also submitted fee of Rs.30000/- vide challan No. 334402505, verified from website, as pre-registration variation fee. Firm has also submitted original fee challan of Rs.8000/- and yellow copy of fee challan of Rs.12000/- in lieu of verification of fee challan. Hence, formulation may be corrected as per reference. Accordingly, correct formulation is as under:

"Each gram contains:

Fluocinolone acetonide…….0.01%
Hydroquinone……...4%
Tretinoin……0.05%"

Decision: **Registration Board decided to approve the correction in above product with following details.**

"Each gram contains:
Fluocinolone acetonide…….0.01%
Hydroquinone……...4%
Tretinoin……0.05%"

iii. M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha

Registration Board in its 323rd meeting approved following registration application of M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha. Detail is under:

Name and address of manufacturer / Applicant	M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha
Brand Name +Dosage Form + Strength	Roso 20mg Tablet
Composition	Each Tablet Contains: Rosuvastatin…20mg
Diary No. Date of R& I & fee	Dy No. 16665: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	HMG CoA reductase 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	Crestat Tablet by CCL
GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
Remarks of the Evaluator[3].	• Firm has revised the label claim as per the innovator's product along with submission of full fee 30,000/- (vide slip number 48933741286) dated 23-11-2022 as per following: Each Film Coated Tablet Contains: Rosuvastatin (as calcium)..…20mg
Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin (as calcium)..…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	

While processing registration letter it was transpired that applied strength of the product is 20mg while in decision of the Board it was mentioned as 10mg. Hence, correction ids required in decision of the Board. Firm has also submitted GMP Certificate issued dated 22-08-2022. Accordingly, correct formulation is as under:

"Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)..…20mg"

Decision: **Registration Board decided to approve the correction in above product with following details.**

"Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)..…20mg"

iv. M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore.

Registration Board in its 321st meeting approved following registration application of M/s Ameer Pharma 23 KM-Sheikhupura Road, Lahore. Detail is under:

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

While processing registration letter it was transpired that applied strength of the product is 40mg while in decision of the Board it was mentioned as 10mg. Hence, correction ids required in decision of the Board. Firm has also submitted Firm has submitted revised label claim along with master formulation and fee of Rs.30,0000/-", [Rs.7500/-, vide challan No. 666070574000 and Rs.22500/- vide challan No. 58992619140, verified from website. Accordingly, correct formulation is as under:

"Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)..…40mg"

Decision: Registration Board decided to approve the correction in above product with following details.

"Each Film Coated Tablet Contains:
Rosuvastatin (as calcium)..…40mg"

v. M/s Crystolite Pharmaceuticals, Plot # 1& 2, Street S-2, National Industrial Zone, Rawat.

Registration Board in its 271st meeting approved following registration application of M/s Crystolite Pharmaceuticals, Plot # 1& 2, Street S-2, National Industrial Zone, Rawat. Detail is under:

Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals, Plot # 1& 2, Street S-2, National Industrial Zone, Rawat.
Brand Name +Dosage Form + Strength	Dolopro gel 0.05%
Diary No. Date of R& I & fee	Dy No.2458; 25-07-2014; Rs.20,000/-
Composition	Each gram contains:-

	Piroxicam... 0.5% w/w
Pharmacological Group	NSAID
Type of Form	Form-5
Finished Product Specification	USP
Pack size & Demanded Price	1's (15gm tube and 30gm tube); As per PRC
Approval status of product in Reference Regulatory Authorities.	MHRA approved
Me-too status	Pharox gel of Valor Pharma
GMP status	Last GMP Inspection of M/s Crystolite Pharmaceuticals conducted on 18-01-2017 with conclusive remarks of good level of cGMP compliance.
Remarks of the Evaluator.	i. Primary packaging material of applied formulation is plastic tube while in MHRA it is Aluminum tube; however the firm has submitted commitment that the firm will conduct and submit complete stability studies to the DRAP with these plastic tubes to justify that our product is stable with these plastic tubes. ii. Firm has cream, ointment and lotion (general, steroidal section) now in which section gel has to be manufactured, is there any requirement of separate section for manufacturing of gels. iii. Firm has claimed USP specifications while applied formulation is not present in USP.
Decision: Approved.	

Registration letter of above product was not issued due to clarification of strength of formulation as in brand name it was mentioned as 0.05% while in formulation it was mentioned as 0.5%. Now firm has submitted receiving of registration application which reveals that applied strength is 0.5%. Hence, correct formulation is as under:

"Dolopro gel 0.5%
Each gram contains:
Piroxicam.....0.5% w/w"

Decision: **Registration Board decided to approve the correction in above product with following details.**

"Dolopro gel 0.5%
Each gram contains:
Piroxicam.....0.5% w/w"

Case No.03: Cancellation of Registration of Drugs of M/s. Hoover Pharmaceuticals (Pvt) Ltd. Plot No.16 Zain Park Industrial Area Saggain By Pass Road Lahore.

M/s. Hoover Pharmaceuticals (Pvt) Ltd. Plot No.16 Zain Park Industrial Area Saggain By Pass Road Lahore has submitted a request regarding cancellation of registration of their following 04 products. Detail is as under;

Sr. No.	Reg. No.	Brand Name of Product	Justification
1.	087568	Mutorol Granular Powder Each sachet contains: Acetylcysteine…….200mg	i. Cost of active material, excipient, packaging material, process cost and marketing expense exceeds from market price of product they are requesting for cancellation of registration of these products. ii. No market demand.
2.	087569	Vigabet 500mg Sachet Each sachet contains: Vigabatrin……500mg	
3.	087576	Ferodol-P Syrup Each 5ml contains: Iron Protein Succinylate 800mg eq. to Elemental Iron…….40mg	
4.	069330	Dewart Dispersible Tablets Each tablet contains: Artemether…….20mg Lumefantrine…….120mg	

Firm has submitted following documents;

1. Copy of registration letter and last renewal status.
2. List of alternatives brands/FPPs available in the country.

3. An undertaking regarding no case is pending at any forum/court of law of regarding above mentioned products and provided information/documents are true/correct.

Decision: Registration Board decided to call M/s. Hoover Pharmaceuticals (Pvt) Ltd. Plot No.16 Zain Park Industrial Area Saggain By Pass Road Lahore for personal hearing under section 42 of Drugs Act 1976 schedule VI of DRAP Act 2012.

Post Registration-I Section

1. Regularization of Renewal Status Instead of Extension in Contract Manufacturing Permission of Registered Drugs.

M/s **Atco Laboratories Limited, B-18, S.I.T.E., Karachi** applied for regularization of renewal status of their registered products being imported in bulk and locally repacked. The firm submitted that their previous permission was valid till 12-12-2022 and now they are applying for regularization of registration in light of decision of 316th meeting of Registration Board in case of M/s Martin Dow Limited, Karachi wherein the Board decided as follows:

"Registration Board acceded to request of firm for regularization of renewal status of firm from initial date of registration as subsequent permission is post-registration variation and will not be considered towards renewal of drug product."

The details of applications for regularization are as under:

Sr. No.	Brand Name, Composition & Reg. No.	History of Registration & Post registration variations	Documents submitted
1.	Hrudoid Cream Each 100gm contains: Mucopolysaccharide polysulphuric acid ester…….0.3g (Reg. No. 014995)	i. Initial Reg. Letter No. F. 3-2/94-REG-I (107-M) dated 15-06-1994 ii. Copy of renewal application submission dated 17-05-2019 iii. Copy of approval name change of foreign manufacturer dated 12-08-1998 iv. Copy of approval letter of change from finished import to bulk import, local repacking dated 29-04-2003 valid for 18 months. v. Copy of approval letter for extension in permission of bulk import local repacking dated 03-02-2005 valid for 06 months. vi. Copy of one time permission of bulk import local repacking dated 13-09-2007. vii. Copy of approval letter for extension in permission of bulk import local repacking dated 21-02-2008 valid for two years. viii. Copy of approval letter of name change of bulk manufacturer from M/s Sankyo Pharma to M/s Daiichi Sankyo Europe GmbH dated 18-05-2010. ix. Copy of approval letter of name change of bulk manufacturer from M/s Daiichi Sankyo Europe GmbH to M/s Mobilat Producktions GmbH dated 16-11-2011. x. Copy of approval letter for extension in permission of bulk import local repacking dated 13-12-2012 valid for 05 years. xi. Copy of approval letter for extension in permission of bulk import local repacking dated 03-09-2020 valid till 12-12-2022.	Application Dy. No. 34728 (R&I) dated 30-11-2022. Rs. 150000/- dated 17-11-2022. Registration Trail.
2.	Hrudoid Gel Each 100gm contains: Mucopolysaccharide polysulphuric acid ester…….300mg (Reg. No. 017481)	i. Initial Reg. Letter No. F. 3-2/95-REG-I (M-113) dated 13-07-1995 ii. Copy of renewal application submission dated 23-06-2020 iii. Copy of approval name change of foreign manufacturer dated 12-08-1998 iv. Copy of approval letter of change from finished import to bulk import, local	Application Dy. No. 34728 (R&I) dated 30-11-2022. Rs. 150000/- dated 17-11-2022. Registration Trail.

		repacking dated 29-04-2003 valid for 18 months. v. Copy of approval letter for extension in permission of bulk import local repacking dated 03-02-2005 valid for 06 months. vi. Copy of one time permission of bulk import local repacking dated 13-09-2007. vii. Copy of approval letter for extension in permission of bulk import local repacking dated 21-02-2008 valid for two years. viii. Copy of approval letter of name change of bulk manufacturer from M/s Sankyo Pharma to M/s Daiichi Sankyo Europe GmbH dated 18-05-2010. ix. Copy of approval letter of name change of bulk manufacturer from M/s Daiichi Sankyo Europe GmbH to M/s Mobilat Producktions GmbH dated 16-11-2011. x. Copy of approval letter for extension in permission of bulk import local repacking dated 13-12-2012 valid for 05 years. xi. Copy of approval letter for extension in permission of bulk import local repacking dated 03-09-2020 valid till 12-12-2022.	
3.	Movelat Gel 100gm Adrenocortical extract…..1gm Mucopolysaccharide polysulphate…….300mg Salicylic Acid…..2gm (Reg. No. 017482)	i. Initial Reg. Letter No. F. 3-2/95-REG-I (M-113) dated 13-07-1995 ii. Copy of renewal application submission dated 23-06-2020 iii. Copy of approval name change of foreign manufacturer dated 12-08-1998 iv. Copy of approval letter of change from finished import to bulk import, local repacking dated 12-11-2002 valid for 18 months. v. Copy of approval letter for extension in permission of bulk import local repacking dated 22-07-2004 valid for 18 months. vi. Copy of one time permission of bulk import local repacking dated 13-09-2007. vii. Copy of approval letter for extension in permission of bulk import local repacking dated 21-02-2008 valid for two years. viii. Copy of approval letter of name change of bulk manufacturer from M/s Sankyo Pharma to M/s Daiichi Sankyo Europe GmbH dated 18-05-2010 ix. Copy of approval letter for extension in permission of bulk import local repacking dated 13-12-2012 valid for 05 years. x. Copy of approval letter for change in name of bulk manufacturer along with extension in permission of bulk import local repacking dated 08-05-2019 valid till 12-12-2022.	Application Dy. No. 34728 (R&I) dated 30-11-2022. Rs. 150000/- dated 17-11-2022. Registration Trail.

Decision: Registration Board acceded to request of firm for regularization of renewal status of firm from initial date of registration as subsequent permission is post-registration variation and will not be considered towards renewal of drug product.

2. Application for change in name of already registered drug product applied by M/s Sigma Pharma International Pvt. Ltd., Karachi.

Sr. #	Reg. No.	Name of Brand Name with composition	Proposed Brand Names	Date of Initial Reg. & Date of Renewal	Justification / Remarks/ Deficiency (if any)
1.	079912	Sixil 10mg/g Gel Each gm contains: Clindamycin phosphate equivalent to clindamycin…….10mg/g USP Specification	CLINDACURE	03.04.2015 03.04.2020	Fee Rs.30,000/-deposited on 07.09.2022 dy.no.27171-PR-I dated 26.09.2022 **Justification**: As per marketing department requirement.

Decision of 87-PRVC: *The Committee considered the case and deferred the request for submission of more brand names.*

Fresh Submission: *The firm has submitted copy of following Decision 91st DRAP Authority meeting dated 03.12.2020.*

"Same brand name may be granted to different manufacturers/importers for different dosage forms having same active pharmaceutical ingredient (API) subject to agreement between them/NOC by prior registration holder."

Original NOC from Hiranis Pharmaceuticals (Pvt) Limited is also provided.

Decision of 93-PRVC: *The Chairman Registration Board on the recommendation of the Committee deferred the request of the firm for submission of more brand names without suffix "cure".*

Fresh Submission:

The firm has submitted copy of following Decision of 98th DRAP Authority meeting dated 03.12.2020.

"Same brand name may be granted to different manufacturers/importers for different dosage forms having same active pharmaceutical ingredient (API) subject to agreement between them/NOC by prior registration holder."

Decision of 97th PRVC:

"*The Chairman Registration Board on the recommendation of the Committee referred the case to Registration Board for further deliberation."*

Decision: The Registration Board deferred the request of the firm and advised the division of PE@ R to bring the matter of grant of brand names in Toto in consultation with stakeholders keeping in view the regional and International practices.

3. Request for cancellation of registration by M/s. Sanofi Aventis Pakistan Limited, Karachi.

The Firm has stated that." *We have been informed by the manufacturing site Sanofi-aventis Ddeuctschland GmbH, Brueningsrasse 50, D-65926 Frankfurt am Main, Germany that they have decided to withdraw registration license of* ***Tarivid I.V 200mg infusion*** *due to a business decision. This decision is not related to safety, quality and efficacy of the product. Enclosed is the letter as received form Global head office for the same. Whereas Tarivid Tablets 200mg(Reg No.009462) and many alternates of Tarivid IV Infusion are freely available in the market some examples are given below:-*

Sr.#	Alternate Brands	INN	Manufacturer
1.	Tariflox Infusion 200mg/100ml	Ofloxacin	M/s Bosche
2.	Oflobid Infusion		M/s Hilton Pharma
3.	Adios Infusion		M/s Wilshire Lab.

The firm has submitted the registration trail of above product.

Decision of 97th PRVC:

"*The Chairman Registration Board on the recommendation of the Committee referred the case to Registration Board."*

Decision: The Registration Board decided to give opportunity of personal hearing to M/s Sanofi Aventis Pakistan Limited, Karachi under Section 42 of The Drugs Act, 1976.

Export Facilitation Desk

1. Registration of Drug (s) of M/s Safe Pharmaceuticals (Pvt.) Ltd, Plot No. C-1-20, Sector 6-B, North Karachi 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 02-6/92-Lic dated 11-06/2008
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 19-09-2022
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.	Monzine-Safe 5mg/10 Tablet Each un coated tablet contains: Levocetirizine Dihydrochloride (USP).....5mg Montelukast sodium (USP) eq. to Montelukast.....10mg	Purchase order from Yemen	Dy. No. 128(03.03.2023) Rs.30,000/- (24.11.2022) Rs.45,000/- (13.02.2023)

Decision: The Registration Board deferred the case for submission of evidence of approval and market availability of formulation in the country of import.

Import & Vet-I Section

Case No.01:- Request of M/s. Star Laboratories (Pvt) Ltd, Lahore for Correction of Composition/Finished Product Specifications of already Registered Veterinary Drug.

M/s. Star Laboratories (Pvt) Ltd, Lahore for correction of composition/finished product specifications already registered veterinary drug of their following registered drug as per detail mentioned against each:-

S. No.	Regn. No.	Product Granted Composition	Demanded Composition/Demanded Finished Product Specifications	Remarks/ Diary No. R&I & Initial date of Regn.
I	II	III	IV	V
1.	008032	Penivet-5 Injection (Composition not mentioned as per initial registration letter)	Penivet-5 Injection Each vial contains:- Benzyl Penicillin…….500000 IU Procaine Penicillin1…500000 IU Streptomycin Sulphate……...5gm (As per Innovator's Specifications)	Dy. No. 36752-R&I dated 16-12-2022. 27-02-1985 13-01-2020

M/s. Star Laboratories (Pvt) Ltd, Lahore has deposited the required fee of **Rs.30,000/-** for correction of composition and submitted following supporting documents:-

(i) Copy of Registration letter/ renewal trail.
(ii) Copy of CRF.
(iii) Label.

The composition in initial registration letter is not mentioned. The firm has requested to issue corrigendum of registration letter against the above mentioned composition with specifications.

The Post Registration Variation Committee in its 95th meeting and the committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided to refer the case to Registration Board.

Decision: - Registration Board refer the case to Renewal Section for confirmation of composition from renewal record.

Case No.02: - Refer Cases (M-323) Meeting to Licensing Division for Confirmation of Manufacturing Facility for Intra mammary Injection of M/s. Selmore Pharmaceuticals (Pvt) Ltd, Lahore.

1.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cefagent-AD LC Intramammary Suspension
	Composition	Each 10ml contains:- Cephalexin Monohydrate (Base)…..200mg Gentamicin Sulphate (Base)….....100mg Dexamethasone-21 phosphate……..0.75mg Vitamin A……..10,000 IU
	Diary No. Date of R& I & fee	Rs.30,000/- (20991/26.07.2022)
	Pharmacological Group	Antibiotic-Anti-inflammatory combination
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	48 Injectors of 10ml / Decontrolled
	Me-too status	Cefa Milk Forte Intramammary Suspension Registration No: 053955, by M/s Mustafa Brothers Faisalabad
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Cephalexin and Gentamicin salt form presentation is not as per reference
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syrine filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board referred the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections**	
Accordingly letter issued to Licensing Division for confirmation of Intra mammary Injection facility. In response the Licensing Division has attached sections. The firm has provided an updated list of the machinery which shows that they have syringe filling machine (Intra mammary). **Decision:- Approved.**		
2.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Uteprim Intrauterine Suspension
	Composition	Each 19gm syringe contains:- Cephapirin as benzathine……..500mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20992/26.07.2022)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10 Injectors of 19gm / Decontrolled
	Me-too status	Metricure Intrauterine Suspension Registration No: 078355.by ICI Pakistan, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections.	

	The firm has provided detail of Syrine filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
Accordingly letter issued to Licensing Division for confirmation of Intra mammary Injection facility. In response the Licensing Division has attached sections. The firm has provided an updated list of the machinery which shows that they have syringe filling machine (Intra mammary). **Decision:- Approved.**		
3.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cepramast DC Intramammary Suspension
	Composition	Each 3gm syringe contains:- Cefalonium…….250mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20994/26.07.2022)
	Pharmacological Group	Cephalosporin Antibiotic.
	Type of Form	Form-5
	Finished product Specification	BP-Vet Specifications
	Pack size & Demanded Price	24 Injector of 3mg / Decontrolled
	Me-too status	Cepravin Intramammary Suspension Registration No: 020133 by ICI Pakistan, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Reference presentation: Cefalonium 250mg (as cefalonium dihydrate)
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
Accordingly letter issued to Licensing Division for confirmation of Intra mammary Injection facility. In response the Licensing Division has attached sections. The firm has provided an updated list of the machinery which shows that they have syringe filling machine (Intra mammary). **Decision:- Approved.**		
4.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Redycef LC Intramammary Suspension
	Composition	Each 10ml syringe contains: Ceftiofur as Hydrochloride…… 125mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20995/26.07.2022)
	Pharmacological Group	Broad-spectrum Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	Innovators Specifications
	Pack size & Demanded Price	12 Injectors of 10ml / Decontrolled
	Me-too status	Spectra Mast LC Intramammary Suspension Registration No: 088652.by M/s. Ghazi Brothers, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections.	

	The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
Accordingly letter issued to Licensing Division for confirmation of Intra mammary Injection facility. In response the Licensing Division has attached sections. The firm has provided an updated list of the machinery which shows that they have syringe filling machine (Intra mammary). **Decision:- Approved.**		
5.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Redycef DC Intramammary Suspension
	Composition	Each 8ml syringe contains: Ceftiofur as Hydrochloride……500mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20996/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	Innovators Specifications
	Pack size & Demanded Price	5 Injectors of 8ml / Decontrolled
	Me-too status	Cefent DC Intramammary Suspension Registration No: 093830 by M/s UM Enterprises, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
Accordingly letter issued to Licensing Division for confirmation of Intra mammary Injection facility. In response the Licensing Division has attached sections. The firm has provided an updated list of the machinery which shows that they have syringe filling machine (Intra mammary). **Decision:- Approved.**		
6.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cefagent LC Intramammary Suspension
	Composition	Each 10ml syringe contains:- Cefalexin as Monohydrate…….350mg Gentamicin as Sulphate……35mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20993/26.07.2022)
	Pharmacological Group	Antibiotic Combination.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	24 Injectors Of 10ml / Decontrolled
	Me-too status	Mastilex Intramammary Suspension Registration No: 019980. by M/s. Vetaria Pharmaceuticals, Lahore
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K	

	in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**

Accordingly letter issued to Licensing Division for confirmation of Intra mammary Injection facility.

In response the Licensing Division has attached sections. The firm has provided an updated list of the machinery which shows that they have syringe filling machine (Intra mammary).

Decision:- Approved.

Case No.03:- Refer cases (M-323) meeting deferred for clarification regarding intended use / indication of applied formulation of M/s. Selmore Pharmaceuticals (Pvt) Ltd, Lahore.

1.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Prokill Powder
	Composition	Alkyl (60% C_{14}, 30% C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chloride… 40%. Inert Ingredient: urea……...60%
	Diary No. Date of R& I & fee	Rs.30,000/- (21009/26.07.2022)
	Pharmacological Group	External Powder Preparation (Disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specifications
	Pack size & Demanded Price	250g , 500g , 1Kg , 5Kg / Decontrolled
	Me-too status	TIMSEN Powder Registration No: 043101 by M/s. Ghazi Brothers, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too not same as applied product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The firm has revised the formulation according to reference product as: Alkyl (60% C14, 30% C16, 5%C12, 5%C18) dimethyl Benzyl ammonium chloride… 40% and deposited the Fee of Rs. 30000/- vide bank deposited Slip No. **5747962544** dated **16.09.2022** **Decision:- Deferred for clarification regarding intended use / indication of applied formulation.** **Firm submitted Indications** of PROKILL i.e. It is a complete biocide, highly effective for environment and equipment disinfection even in the presence of organic material. Effective for poultry, swine, goat and aquaculture.	
Decision:- Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.		
2.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Septisel 10% Solution
	Composition	Each Litre contains:- Di-decyl-di-methyl-ammonium bromide….10%
	Diary No. Date of R& I & fee	Rs.30,000/- (21004/26.07.2022)
	Pharmacological Group	External Liquid Preparation (disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1 Litre, 2.5 Litre, 5 Litre / Decontrolled
	Me-too status	BROMO-SEPT Solution. Registration No: 017054, by M/s SELMORE AGENCIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022

	Remarks of the Evaluator.	Generic is not same as applied.
	Decision: Deferred for clarification regarding intended use / indication of applied formulation. **Firm submitted Indications of** SEPTISEL10% solution i.e. It is used as disinfectant against gram (+/-) bacteria, spore-forming bacteria, fungi, yeast, pathogenic viruses and mycoplasma	
Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its legal status in regional and global regulatory authorities.		

Case No. 04:- Reconstitution of Expert Working Group on Veterinary Drugs

Drug Registration Board in its 281st meeting held on 11-13th April, 2018 has constituted expert working group on veterinary drugs regarding matters related to veterinary drugs.

Decision of 281st meeting of RB: -

The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised for inclusion of relevant expert(s) member(s) of the Board etc. However, since process of revision of constitution may take some time as the approval of Federal Government and other relevant organizations are required before revised Gazette notification, so, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring input/recommendation of pertinent veterinary expert, the Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -

1.	*Dr. Qurban Ali, Ex-Director General* *National Veterinary Laboratory, Islamabad.* *Expert Member Veterinary Drugs*	*Chairman*
2.	*Animal Husbandry Commissioner or his representative,* *M/o National Food Security & Research, Islamabad.*	*Member*
3.	*Dr.Mazhar-ul-Haq* *Veterinary Pharmacologist* *Arid Agriculture University, Rawalpindi.*	*Member*
4.	*Any other relevant expert(s)*	*As Co-opted member(s)*
5.	*Deputy Director (Reg-I), DRAP*	*Member, Secretary*

The expert working group will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations. The group can Co-opt any relevant expert(s) as Co-opted member(s).

The Board further advised that in order to avoid any pendency, the "expert working group" needs be notified immediately without waiting till formal approval of the minutes of 281st meeting so that the meeting of the expert working group may be called earlier.

Accordingly notification of expert working group was issued on 08th May 2018. Chairman of Expert working Group co-opted Dr. Shabnum Firdous, Secretary PVMC as a co-opted member, and letter for in this regard was issued on 16th June 2022.

After completion of 2nd term Dr. Qurban Ali, (Chairman EWG) was retired as member registration board [under Rule 24 (f) of Drugs (LR&A) Rules, 1976 (Expert Member for Veterinary Drugs)]. Accordingly denotification letter of EWG, after approval from Chairman, Registration Board, was issued on 24th February, 2023 vide letter No. 7-4/2018 (M-281) and endorsed in 325th meeting of Registration Board.

Decision:- The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised in order to avoid pendency/delay in processing of issues relating to veterinary drugs which require input/recommendation of pertinent veterinary expert, hence Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition:-

1.	**Dr. Qurban Ali,** **Ex-Director General,** **National Veterinary Laboratory, Islamabad.**	**Chairman**
2.	**Dr. Ayesha Yaqoob, Drug Testing Laboratory,** **Rawalpindi.**	**Member**
3.	**Mst. Najia Saleem, Deputy Director (PE&R), DRAP**	**Member**

4.	Any other relevant expert(s)	As Co-opted member(s)
5.	Assistant Director (I&V-I), DRAP	Member, Secretary

The expert working group will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations. The group can Co-opt any relevant expert(s) as Co-opted member(s).

The Board further advised that in order to avoid any pendency, the "expert working group" needs be notified immediately without waiting till formal approval of the minutes of 281st meeting so that the meeting of the expert working group may be called earlier.

Import & Vet-II Section

Case No: 01 REQUEST OF M/S ALI GOHAR & COMPANY (PVT) LTD, KARACHI FOR GRANT FOR ONE TIME PERMISSION FOR RE-PRINTING REVISED PRICES ON ALREADY PRIENTED PACKAGING OF IMPORTED DRUG.

M/s Ali Gohar & Company (Pvt) Ltd, State Life Building 1-B I.I. Chundrigar Road, Karachi has requested for grant of one-time permission for re-printing of revised MRPs on already printed packaging for their product Systane Lubricant Eye Drops (Reg. No.044834) which is imported in December 2022 and January 2023. Details are as under; -

Name of Product	Reg. No.	Manuf. Date	Batch No.	Batch Size	MRP already printed	Existing approved MRP
Systane Lubricant Eye Drops Contains:- Polyethylene Glycol 400…..0.4%w/v Propylene glycol…….0.3% w/v	044834	30-09-2022 30-10-2022 05-08-2022 21-11-2022 23-11-2022	11574 11F1W 11A6W 11ATP 11FKM	47,232 20,888 33264 12816 6912	Rs.998.87	Rs.1098.76

As per Drug Pricing Policy Section 3. Basis of Pricing Sub-section (6) No person including a manufacturer, importer, retailer, hospital, clinic, wholeseller or distributor shall be allowed to fix stickers, overlapping or masking of prices. However, in case of voluntary reduction in MRP, masking of previous MRP and reprinting of reduced MRP through laser inkjet will be permissible, if so required.

Decision: The Registration Board considered the request of the company and after detailed discussion and deliberations, the board didn't accede to the firm request.

RRR Section

Case No. 1 Renewal application of the products which require confirmation of manufacturing facility

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
M/s. Elko Organization (Private) Ltd. 27 & 28, Sector 12/B North Karachi Industrial Area Karachi					
1.	020250	Viscogel Contains: Hydroxy Propyl Methyl Cellulose.....2%	14/10/1997	Dy. No. 28594 dated 07-02-2021 Rs. 15000/-	The approved pack is 2ml syringe. The revised layout plan approved vide DRAP letter 2-5/84-Lic (Vol-VI) dated 16.11.2021 does not indicate facility.

2.	20251	Viscogel HV Contains: HydroxyPropyl Methyl Cellulose.....2%	14/10/1997	Dy. No. 28594 dated 07-02-2021 Rs. 15000/-	The approved pack is 2ml syringe. The revised layout plan approved vide DRAP letter 2-5/84-Lic (Vol-VI) dated 16.11.2021 does not indicate facility.
3.	20254	Hair Max Each ml contains: Minoxidil.....20mg Denatured Spirit...0.6ml Propylene-glycol .0.1ml Purified Water q.s. to 1ml	14/10/1997	Dy. No. 28594 dated 07-02-2021 Rs. 15000/-	The revised layout plan approved vide DRAP letter 2-5/84-Lic (Vol-VI) dated 16.11.2021 does not indicate external preparation facility
Decision:	**Registration Board deferred above renewal applications for confirmation of approval of manufacturing facility from Licensing Division.**				
M/s. Lahore Chemical & Pharmaceutical Works (Pvt) Ltd.,137-Shahrah-e-Moulana Jalal ud din Roomi Lahore. (DML No.000064)					
4.	003440	Prednisolone tablet Each tablet contains: Prednisolone B.P…….5mg	05-01-1978	Dy. No. 34878 dated 01-12-2022 Rs. 15000/-	The GMP certificate dated 18.10.2019 does not indicate facility for Tablet Steroids.
Decision:	**Registration Board deferred above renewal applications for confirmation of approval of manufacturing facility from Licensing Division.**				
M/s Panacea Pharmaceuticals Plot no. 4 Street S-6, National industrial Zone Rawat Islamabad					
5.	075204	Tiram 250mg Suspension Each 5ml contains: Levetiracetam…250 mg (Panacea Spec's)	14.02.2013	Dy. No. 3290 dated 03.02.2023 Rs. 15000/- vide slip No. 9372346192	As per submitted Form 5B, the firm is manufacturing dry powder suspension. The applied in aforesaid dosage form is not approved in reference regulatory authorities. The Innovator Product (Keppra by UCB Inc., USFDA/MHRA) is oral liquid/ solution formulation.
Decision:	**Registration Board deferred above renewal applications for clarification from the firm as the applied formulation is dry powder suspension and Innovator is oral liquid/ solution formulation.**				

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 Vetz Pharmaceutical (Pvt) Ltd., Plot No. Q-1 SITE Kotri Sindh					
6.	085493	G MOX 50ML INJECTION Each ml contains Amoxicillin trihydrate eq. to Amoxicillin….50 mg- Gentamicin sulphate eq. to Gentamicin…..25 mg	14.12.2022	Dy No.3018-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027

		(As per Innovators Specifications)			
7.	085492	MOXIL-C 100ML INJECTION Each ml contains: Amoxicillin Trihydrate 137.74mg eq. To Amoxicillin base 120mg Colistin Sulphate…...300,000 IU (As per Innovators Specifications)	14.12.2022	Dy No.3017-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
8.	085491	MOXIL-C 50ML INJECTION Each ml contains: Amoxicillin trihydrate eq. to Amoxicillin 140mg Colistin Sulphate 0.3MIU (As per Innovators Specifications)	14.12.2022	Dy No.3016-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
9.	085490	AMCOVETZ 100ML LIQUID INJECTION Each ml contains: Amoxicillin Trihydrate 114.78mg eq. to Amoxicillin base 100mg Colistin Sulphate 250,000 IU (As per Innovators Specifications)	14.12.2022	Dy No.3015-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
10.	085489	AMCOVETZ 50ML LIQUID INJECTION Each ml contains: Amoxicillin Trihydrate 114.78mg eq. to Amoxicillin base 100mg Colistin Sulphate 250,000 IU (Eq. to 12.20mg approximately) (As per Innovators Specifications)	14.12.2022	Dy No.3014-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
11.	085488	PROCILLIN POWDER INJECTION Each vial contains: Benzyl Penicillin (10,00,000 IU) 0.6 gm Procaine Penicillin (30,00,000 IU) 3.0 gm (As per Innovators Specifications)	14.12.2022	Dy No.3003-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
12.	085487	CLAVIMOX ORAL POWDER Each gm contains: Amoxicillin as Amoxicillin Trihydrate 160 mg Clavulanic Acid 40 mg (As per Innovators Specifications)	14.12.2022	Dy No.3004-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
13.	085486	CLAVICILLIN PLUS ORAL POWDER Each 100gram contains:	14.12.2022	Dy No.3005-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027

		Amoxicillin as Amoxicillin Trihydrate 16 gm Clavulanic Acid as Potassium Clavulanate 4 gm Bromhexine HCl 0.5gm (As per Innovators Specifications)			
14.	085485	BROCAL ORAL POWDER Each 100gram contains: Amoxicillin trihydrate 10gm eq. to Amoxicillin base 8.72gm Lincomycin (as hydrochloride) 5gm Colistin Sulphate 50MIU (As per Innovators Specifications)	14.12.2022	Dy No.3006-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
15.	085484	V-MOX 60% ORAL POWDER Each 1000gm contains: Amoxicillin trihydrate (BP) eq. to Amoxicillin 600gm (As per Innovators Specifications)	14.12.2022	Dy No.3012-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
16.	085483	V-MOX 70% ORAL POWDER Each 1000gm contains Amoxicillin trihydrate (BP) eq. to Amoxicillin 700gm (As per Innovators Specifications)	14.12.2022	Dy No.3013-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
17.	085482	AMICOSIN E ORAL POWDER Each gm contains: Amoxicillin trihydrate 229.56mg eq. to Amoxicillin base 200 mg Lincomycin HCl 99.792mg equivalent to Lincomycin base 88 mg Spectinomycin Sulphate 113.96mg eq. to Spectinomycin base 88 mg (As per Innovators Specifications)	14.12.2022	Dy No.3002-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
18.	085481	VETMOXIL PLUS ORAL POWDER Each 100gram contains: Amoxicillin Sodium 23gm eq. to Amoxicillin base 21.70gm Colistin Sulphate 100 MIU (As per Innovators Specifications)	14.12.2022	Dy No.3011-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
19.	085480	VETMOXIL ORAL POWDER Each 100gram contains: Amoxicillin Trihydrate eq. to Amoxicillin base 15 gm Colistin Sulphate 50MIU	14.12.2022	Dy No.3010-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027

		(As per Innovators Specifications)			
20.	085479	VETMOXIL ORAL POWDER Each gram contains: Amoxicillin as sodium….100mg Colistin Sulphate…. 500,000 IU (As per Innovators Specifications)	14.12.2022	Dy No.3009-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
21.	085478	AM-BIOTIC-C ORAL POWDER Each 100gram contains: Amoxicillin as Amoxicillin Trihydrate_ 20 gm Colistin Sulphate 50MIU (As per Innovators Specifications)	14.12.2022	Dy No.3008-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
22.	085477	AMBIOTIC PLUS ORAL POWDER Each 100gram contains Amoxicillin Trihydrate 20gm eq. to Amoxicillin base 17.43gm Colistin Sulphate 80MIU	14.12.2022	Dy No.3007-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
23.	085476	AL-SPEC ORAL POWDER Each 100gram contains Amoxicillin trihydrate 10gm eq. to Amoxicillin base 8.72mg Lincomycin base 5gm Spectinomycin Base 5gm (As per Innovators Specifications)	14.12.2022	Dy No.3003-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
24.	085475	ALMYCIN ORAL POWDER Each 100gram contains Amoxicillin Trihydrate 20gm eq. to. Amoxicillin base 17.43gm Lincomycin base 8.8gm Spectinomycin base 8.8 gm	14.12.2022	Dy No.3001-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
25.	85724	G MOX 100ML INJECTION Each ml contains Amoxicillin trihydrate eq. to Amoxicillin 50mg Gentamicin sulphate eq. to Gentamicin_ 25 mg (As per Innovators Specifications)	14.12.2022	Dy No.3019-R&I Dated 02.02.2023 Rs.30000/-	Renewal is granted w.e.f 14.12.2022 to 13.12.2027
M/s Medicraft Pharmaceuticals Pvt Limited, 126-Industrial Triangle Hayatabad Peshawar.					
26.	021838	Nap-500 Tablets Each tablet contains: Naproxen BP…..500mg	23.08.1998	10000/- dated 29.05.2013 Rs. 10000 dated 10.05.2018 Dy. No. 3626 dated: 08.02.2023	Renewal is granted w.e.f 23.08.2023 to 22.08.2028 The firm shall submit reference of finished product specifications as per

				Rs. 15000/-	decision of 295th meeting of Registration Board.
27.	0218340	Enzovit Syrup Each 5ml contains Pepsin…50mg Pepsin BPC…50mg Vitamin B1…5mg Vitamin B2…2mg Vitamin B6…2mg Vitamin B12…5mcg Nicotinamide…20mg Calcium D-Pantothenate…1mg	23.08.1998	10000/- dated 29.05.2013 Rs. 10000 dated 10.05.2018 Dy. No. 3626 dated: 08.02.2023 Rs. 15000/-	Deferred for evaluation under vitamin policy.
28.	021841	Mediplex-L Syrup Each 30ml contains: Riboflavin (B2)…6mg Thiamine HCl (B1)…6mg Pyridoxine HCl (B6)…4mg Nicotinamide…46mg Lysine Mono HCl…100mg	23.08.1998	10000/- dated 29.05.2013 Rs. 10000 dated 10.05.2018 Dy. No. 3626 dated: 08.02.2023 Rs. 15000/-	Deferred for evaluation under vitamin policy.
29.	021842	Univit-M Tablets Each tablet contains: Vitamin A…1.5mg Vitamin D…12.5mcg Vitamin B1…2.5mg Vitamin B2…2.5mg Ascorbic Acid (Vit.C)…50mg Nicotinamide…20mg Vitamin B6…0.5mg Calcium Pantothenate…5mg Vitamin B12…2mcg Iron (as Ferrous Fumarate)…10mg Iodine (as Potassium Iodide)…0.15mg Copper (as Sulphate)...1mg Manganese (as Sulphate)...1mg Magnesium (as Oxide)...6mg Potassium (as Sulphate)...5mg Calcium (as Carbonate)...35mg	23.08.1998	10000/- dated 29.05.2013 Rs. 10000 dated 10.05.2018 Dy. No. 3626 dated: 08.02.2023 Rs. 15000/-	Deferred for evaluation under vitamin policy.
M/s Heal Pharmaceuticals Pvt Limited, W-33 Industrial Estate Hayatabad Peshawar.					
30.	085918	Loratad Syrup Each 5ml contains: Loratadine….5 mg USP Specifications	28.11.2017	Dy. No. 1921 dated 19.01.2023 Rs. 15000/- Rs.30000/- vide Dy.No.5884 dated 01.03.2023.	Renewal is granted w.e.f 28.11.2022 to 27.11.2027

31.	082625	Hefixim DS Dry Powder Suspension Each 5ml contains: Cefixime as Trihydrate…...200 mg USP Specifications	16.11.2017	Dy. No. 1922 dated 19.01.2023 Rs. 15000/- Rs.30000/- vide Dy.No.5884 dated 01.03.2023.	Renewal is granted w.e.f 16.11.2022 to 15.11.2027
M/s McOlson Research Laboratories Plot No. 2 M-2 Pharma Zone 26Km, Lahore Sharikpur Road Sheikhupura.					
32.	086448	Opigesic 50mg Capsules Each capsule contains: Tramadol HCl…...50mg (USP Specifications)	15.01.2018	Dy. No. 3748 dated 09.02.2023 Rs. 30000/- vide slip No. 32433384	Renewal is granted w.e.f 15.01.2023 to 14.01.2028.
M/s Orta Laboratories Pvt Limited, 24 Km Multan Road Off Defense Road Mohlanwal Lahore.					
33.	048083	Prostaloc Tablets Each tablet contains: Flurbiprofen …. 100mg (BP Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Letter for submission of differential fee for year 2018 and 2023 was issued to the firm vide letter No. 1-65/2018 (RRR) dated 16.02.2023
34.	048084	Dirox Tablets Each tablet contains: Naproxen Sodium …. 550mg (BP Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	-do-
35.	048085	Orpram Tablets Each tablet contains: Escitalopram …. 10mg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	-do-
36.	048086	Diclodyn-K Tablets Each tablet contains: Diclofenac Potassium …... 50mg USP Specifications	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	-do-
37.	048087	Ortabolamin Tablets Each tablet contains: Mecobalamin …. 500mcg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	-do-
38.	048090	Ortabolamin Injection Each vial contains: Mecobalamin …. 500mcg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	-do-
39.	048088	Oramox Tablets Each tablet contains: Moxifloxacin …. 400mg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	-do-
40.	048089	Ortafer Tablets Each tablet contains:	17.01.2008	Dy. No. 2681 dated 27.01.2023	-do-

		Iron III Hydroxide Polymaltose Complex …. 100mg Folic Acid …. 0.35mg (Orta's Specifications)		Rs. 15000/- Rs. 10000/- dated 17.01.2018	
Decision: Registration Board directed to issue show cause notice to the firm for suspension of registration of above products Sr No. 33 to Sr No 40 under section 42 of Drug Act, 1976 and under rule 27 of Drug (LR&A) Rules 1976 considering the fact that the firm has not submitted the prescribed fee of renewal of registration despite of intimation to the firm vide letter No. 1-65/2018 (RRR) dated 16.02.2023 as indicated in the last column above.					
M/s Faas Pharmaceuticals Pvt Limited, F/748-L, S.I.T.E Karachi					
41.	085943	Nomizil Insta Sachet Each sachet contains: Omeprazole……20 mg Sodium bicarbonate….. 1680mg	08.01.2018 Change of BN: 04.07.2019	Dy. No. 2681 dated 27.01.2023 Rs. 30000/-	Renewal is granted w.e.f 08.01.2023 to 07.01.2028.
42.	086085	Nomozil Insta 40mg Sachet Each sachet contains: Omeprazole….40 mg Sodium bicarbonate…...1680mg (As per Innovator's Specifcations)	08.01.2018 Change of BN: 04.07.2019	Dy. No. 2681 dated 27.01.2023 Rs. 30000/-	Renewal is granted w.e.f 08.01.2023 to 07.01.2028.
M/s. Danas Pharmaceuticals (Pvt) Ltd, 312- Industrial Triangle Kahuta Road, Islamabad					
43.	073183	Novel -D 5mg Injection Each ampoule contains: Cholecalciferol …. 5mg (BP Specifications)	01.01.2013	Dy. No. 5754 dated 28.02.2023 Rs. 30000/-	Renewal is granted w.e.f 01.01.2023 to 31.12.2027.
44.	073184	Lidoran Injection Each ampoule 2ml contains: Diclofenac Sodium ….75mg Lidocaine HCI …...20mg (Danas Specifications)	01.01.2013	Dy. No. 5754 dated 28.02.2023 Rs. 30000/-	Renewal is granted w.e.f 01.01.2023 to 31.12.2027. The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
45.	075200	Davira Depot Injection Each ml contains: Medroxy Progesterone Acetate …. 150mg (Danas Specifications)	08.02.2023	Dy. No. 5753 dated 28.02.2023 Rs. 30000/-	Renewal is granted w.e.f 07.02.2023 to 06.02.2028. The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
46.	075201	Danotone Depot Injection Each ml contains: Hydroxyprogesterone Caproate …. 250mg	08.02.2023	Dy. No. 5753 dated 28.02.2023 Rs. 30000/-	Renewal is granted w.e.f 07.02.2023 to 06.02.2028. The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
47.	075205	Norden Tablet Each tablet contains Paracetamol …. 450mg	20.02.2013	Dy. No. 5754 dated 28.02.2023 Rs. 30000/-	Renewal is granted w.e.f 20.02.2023 to 19.02.2028.

		Orphenadrine Citrate…..35mg (Danas Specifications)			The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
48.	075206	Iwill Injection Each ml contains Pheniramine Maleate …. 22.7mg (Danas Specifications)	20.02.2013	Dy. No. 5754 dated 28.02.2023 Rs. 30000/-	Renewal is granted w.e.f 20.02.2023 to 19.02.2028. The firm shall submit reference of finished product specifications as per decision of 295th meeting of Registration Board.
M/s. Stallion Pharmaceuticals (Pvt) Ltd. 581-Sundar Industrial Estate, Lahore Pakistan					
49.	006761-EX	Ampistal 1gm Injection Each vial contains Ampicillin sodium eq to Ampicillin……1gm	18/12.2017	Dy. No. 4153 dated 13.02.2023 Rs. 30000/-	Renewal is granted w.e.f 18.12.2022 to 17.12.2027.
M/s.Mediflow Pharmaceutical (Pvt) Ltd. Plot No.ID 100 Sector 30, Korangi Industrial Area, Karachi					
50.	084689	Flow DS IV Infusion Each 100ml contains Dextrose anhydrous… 5.0gm Sodium chloride…0.90gm- Water for Injection qs to…. 100ml	08/06/2017	Rs.15000/- dated 01.07.2022 Dy. No. 148 Rs. 30000/- dated 02.01.2023 Dy No. 4673 Rs.50000/- dated 13.02.2023	Renewal is granted w.e.f 08.06.2022 to 07.06.2027.
51.	084688	Flow Dex 10% IV Infusion Each 100ml contains Dextrose anhydrous…10.0 gm Water for Injection qs to……..100ml	08/06/2017	Rs.15000/- dated 01.07.2022 Dy. No. 148 Rs. 15000/- dated 05.12.2022 Dy No. 4673 Rs.50000/- dated 13.02.2023	Renewal is granted w.e.f 08.06.2022 to 07.06.2027.
52.	084687	Flow RL IV Infusion Each 100ml contains Sodium chloride….0.6gm Sodium lactate…. 0.32gm Potassium chloride_ 0.04 gm- Calcium chloride 2H2O….0.027gm Water for Injection qs to…. 100ml	08/06/2017	dated 07.08.2022 Rs. 15000/- dated 05.12.2022 Rs. 15000/- Dy No. 4673 Rs.50000/- dated 13.02.2023	Renewal is granted w.e.f 08.06.2022 to 07.06.2027.
53.	084686	Flow Dex 5% Infusion Each 100ml contains Dextrose anhydrous….5.0 gm- Water for Injection qs to….100ml	08/06/2017	Rs.15000/- dated 01.07.2022 Dy. No. 148 Rs. 30000/- dated 02.01.2023 Dy No. 4673 Rs.50000/- dated 13.02.2023	Renewal is granted w.e.f 08.06.2022 to 07.06.2027.
54.	084685	Flow NS IV Infusion Each 100ml contains Sodium chloride….0.90 gm Water for Injection qs to…. 100ml	08/06/2017	Dy. No 34876 dated:01.12.2022 Rs. 30000/-	Renewal is granted w.e.f 08.06.2022 to 07.06.2027.

				Dy No. 4673 Rs.65000/- dated 13.02.2023	
55.	084684	Flow NS IV Infusion Each 100ml contains Sodium chloride…. 0.90 gm Water for Injection qs to….100ml	08/06/2017	Dy. No. 19423 dated 01.07.2022 Rs. 15000/- Dy. No. 34214 Rs. 15000/- dated 05.12.2022 Dy No. 4673 Rs.50000/- dated 13.02.2023	Renewal is granted w.e.f 08.06.2022 to 07.06.2027.
56.	083912	Flow Dex 5% IV infusion Each 100ml contains Dextrose anhydrous….5gm Water for injection….100ml (BP Specifications)	16/06/2017	Dy. No. 19423 dated 01.07.2022 Rs. 15000/- Dy. No. 34214 Rs. 15000/- dated 05.12.2022 Dy No. 4673 Rs.50000/- dated 13.02.2023	Renewal is granted w.e.f 16.06.2022 to 15.06.2027.
M/s. Convell Laboraoties Saidu Sharif Swat					
57.	086124	Fexocon 60mg Tablet Each film coated tablet contains: Fexofenadine hydrochloride…..60 mg (USP Specifications)	29/11/17	Rs.30000/- Dy No.2180 dated 23.01.2023	Renewal is granted w.e.f 29.11.2022 to 28.11.2027.
58.	086123	Velukast 10mg Tablet Each film coated tablet contains: Montelukast as sodium……..10mg (USP Specifications)	29/11/17	Rs.30000/- Dy No.2180 dated 23.01.2023	Renewal is granted w.e.f 29.11.2022 to 28.11.2027.
59.	086122	Velukast 5mg Tablet Each chewable tablet contains: Montelukast as sodium……5mg (USP Specifications)	29/11/17	Rs.30000/- Dy No.2180 dated 23.01.2023	Renewal is granted w.e.f 29.11.2022 to 28.11.2027.

Case No.3 Renewal applications submitted after due date but within one year under SRO 1005(I)/2017.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
M/s News Pharmaceuticals 42—Sundar Industrial Estate Raiwind Road, Lahore					
60.	085027	Lidofin Injection 2ml (IM) Each 2ml contains: Diclofenac sodium….75mg Lignocaine HCl…20mg (As per Innovators Specifications)	19.09.2017	Dy. No. 3835 dated 10.02.2023 Rs. 90000/- vide slip No. 26489512419	Renewal is granted w.e.f 19.09.2022 to 18.09.2027.
M/s Faas Pharmaceuticals Pvt Limited, F/748-L, S.I.T.E Karachi					

61.	082168	Nomizil 20mg Capsule Each capsule contains Omeprazole enteric coated pellets eq. to Omeprazole....20mg (USP Specifications) **Source of Pellets:** M/s Vision Pharmaceuticals Pvt Limited, Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	18.09.2017	Dy. No. 5579 dated 27.01.2023 Rs. 30000/-	Deferred for submission of differential fee Rs.60000/- under SRO 1005(I)/2017. The firm shall deposit the fee within 30 days of intimation of decision.
62.	082167	Nomizil 40mg Capsule Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole...40mg **Source of Pellets:** M/s Vision Pharmaceuticals Pvt Limited, Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	18.09.2017	Dy. No. 5578 dated 27.01.2023 Rs. 30000/-	Deferred for submission of differential fee Rs.60000/- under SRO 1005(I)/2017. The firm shall deposit the fee within 30 days of intimation of decision.
Remarks: Differential fee Rs. 60000/- for each application above need to be submitted. Title of manufacturer pf pellets was changed vide Licensing Division approval letter No. F.1-26/2009-Lic (Vol-II). The firm also submit applicable fee for aforesaid change					

Case No. 4 Renewal applications submitted after prescribed time period.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
Muhammad Hanif & Company, Plot No,D-10, Section 4 Fish Harbbur West Wharf Road, Karachi					
63.	057157	Enrofloxacin 10% Injection Each ml contains Enrofloxacin…100mg **Manufactured By:** M/s. Hebei Yuanzheng Pharmaceuticals Co. Ltd., China	03-06-2009	Dy. No. 34663 dated 30.11.2022 Rs. 30000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
64.	057158	Oxytetracycline 10% Injection Each ml contains Oxytetracycline HCl……100mg **Manufactured By:**	03-06-2009	Dy. No. 34662 dated 30.11.2022 Rs. 30000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27

		M/s. Hebei Yuanzheng Pharmaceuticals Co. Ltd., China			of Drug (LR&A) Rules 1976.
65.	039964	Ivermectin Injection Each ml contains: Ivermectin……..100mg **Manufactured By:** M/s. Hebei Yuanzheng Pharmaceuticals Liability Co. Ltd., China	03-09-2005	Dy. No. 34661 dated 30.11.2022 Rs. 30000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Background of the case: Theabove products were discussed in in 278th meeting of Registration Board and decided as follows: **<u>Enrofloxacin 10% Injection (057157) and Oxytetracycline 10% Injection (057158)</u>** Import from M/s. M/s. Hebei Yuanzheng Pharmaceuticals Co. Ltd., China hence DSL required hence shortcoming letter has been communicated to the firm" **<u>Ivermectin Injection (039964)</u>** Veterinary product "Import from M/s. M/s. Hebei Yuanzheng Pharmaceuticals Co. Ltd., China hence DSL required. Last renewal required (2010-2015). In this regard shortcoming letter has been communicated to the firm. **Remarks:** The renewal application needs to submitted on 02.06.2019 for Enrofloxacin 10% Injection (057157) and Oxytetracycline 10% Injection (057158) and for Ivermectin Injection (039964) needs to be submitted on 02.09.2020. However, the renewal applications were submitted on 30.11.2022, hence invalid as of today.					
M/s. Uni-Tiech Pharmaceuticals (Pvt) Ltd., Plot No. 4/116 Sector 21 Korangi Industrial Area Karachi. (DML No.000356)					
66.	047052	U- Lig 1% Injection Each ml contains: Lignocaine HCl…...10mg (BP Specifications)	05.09.2007	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date (20.03.2022). After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 & 2012 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. It is submitted that the aforesaid application can be considered under SRO 1005(I)/2017 for the period of 2012-2017 however the firm has to submit application before 05-09-2017 for which the evidence of submission is not submitted by the firm. Moreover the renewal application for year 2022 has also been submitted after the due date but within one year.					
67.	015888	Water For Injection	14-09-1994 Transfer of Reg: **22.07.2005**	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020

					under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2014 and 2019 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2019 is not provided by the firm.					
68.	067310	Utine 10mg Tablet Each Tablet contains: Ebastine….10mg	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2020 is not submitted by the firm					
69.	067304	Unilin 50mg Tablet Each tablet contains: Sertraline as HCl…..50mg	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2020 is not submitted by the firm.					
70.	067305	Unilin 100mg Tablet Each Tablet contains: Sertraline as HCl…..100mg	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2020 is not submitted by the firm.					
71.	061142	Unizolid 200mg/100ml Injection Each ml contains: Linezolid……2mg (Manufacturer Specifications)	18-02-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27

					of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2020 is not submitted by the firm.					
72.	061143	Unizolid 400mg/200ml Injection Each ml contains: Linezolid……2mg (Manufacturer Specifications)	18-02-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2020 is not submitted by the firm.					
73.	061144	Unizolid 600mg/300ml Injection Each ml contains: Linezolid……2mg (Manufacturer Specifications)	18-02-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of 2020 is not submitted by the firm.					
74.	045255	Penpra 40mg Tablet Each Tablet contains: Pantoprazole…..40mg	21-03-2007	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 135000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after nine months of due date (20.03.2022). After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 and 2012 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017.The application for renewal for year 2022 need to be submitted on 20.03.2022 but was submitted on 05.12.2022 i.e. after 09 months.					

75.	047054	Sulbacare 1g Dry Powder Injection Each vial contains: Cefoperazone Sodium eq. to Cefoperazone….500mg Sulbactam sodium eq. to Sulbactam…..500mg (USP Specifications)	05-09-2007	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date (20.03.2022). After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 and 2012 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The application for renewal for year 2022 need to be submitted on 04.09.2022 but was submitted on 05.12.2022 i.e. after 03 months.					
76.	047049	CT- Nol 250mg Injection Each 2ml contains: Citicoline….250mg (BP Specifications)	05-09-2007	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Deferred for following: i. Submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date (20.03.2022). ii. Approval of section from Licensing Division. iii. Copy of monograph of BP Specifications After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 and 2012 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The application for renewal for year 2022 need to be submitted on 04.09.2022 but was submitted on 05.12.2022 i.e. after 03 months. The following is still needs to be submitted: i. Approval of section from Licensing Division. ii. Copy of monograph of BP Specifications.					
77.	048669	Unimox 400mg/250ml Infusion	15-07-2008	Dy. No. 35222	Registration Board directed to issue show cause notice

		Each 250ml contains: Moxifloxacin….400mg (Manufacturer Specifications)		dated 05.12.2022 Rs. 15000/-	to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017.The evidence of submission of renewal of year 2018 is not provided by the firm.					
78.	047469	Unistrofer injection Each 5ml contains: Iron sucrose complex eq. to Elemental Iron……20mg (Manufacturer Specifications)	24-01-2008	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2013 & 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. However, no evidence has been submitted in this regard.					
79.	067298	Sodacarbol 50ml Injection Each ml contains: Sodium Bicarbonate….8.4% (USP Specifications)	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not provided by the firm.					
80.	048658	U- Glim 3mg Tablet Each Tablet contains: Glimepiride….3mg (USP Specifications)	15-07-2008	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2013 & 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. However, no evidence has been submitted in this regard.					
81.	067306	Uprinol 100mg Tablet Each Tablet contains: Allopurinol….100mg (USP Specifications)	28-12-2010	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27

					of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is still pending.					
82.	015889	Neurogen 3ml Injection Each 3ml contains: vitamin B1….100mg, vitamin B6….100mg, vitamin B12….1000mg	14-09-1994 Transfer of Reg: **22-07-2005**	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted by the firm.					
83.	067297	Uni- Trops 1mg Injection Each ml contains: Atropine Sulphate…1mg (USP Specifications)	28-12-2010	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted by the firm.					
84.	047468	Xim- Tech 200mg Capsule Each Capsule contains: Cefixime….400mg (USP Specifications)	24-01-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023, however the firm has not submitted any reference.					
85.	048662	Unilol 50mg Tablet Each tablet contains: Atenolol…50mg (USP Specifications)	15-07-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2013 & 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.

Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. However, no evidence has been submitted in this regard.					
86.	048663	Unilol 100mg Tablet Each tablet contains: Celecoxib……..100mg	15-07-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2013 & 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. However, no evidence has been submitted in this regard.					
87.	047048	Cipflke 200mg/100ml Infusion Each 100ml contains: Ciprofloxacin as Lactate…...200mg (USP Specifications)	05-09-2007	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2012 & 2017 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2012 and 2017 vide letter No. F.1-65/2018-RRR dated 26.01.2023. However, no evidence has been submitted in this regard.					
88.	039671	Mortam 1gm Injection Each vial contains: Ceftazidime…..1gm	28-11-2005	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is is not submitted by the firm.					
89.	039670	Mortam 500gm Injection Each vial contains: Ceftazidime….500mg	28-11-2005	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017.The evidence of submission of renewal of year 2020 is not submitted by the firm.					
90.	039669	Mortam 250gm Injection	28-11-2005	Dy. No. 35223 dated 05.12.2022	Registration Board directed to issue show cause notice to the firm for cancellation

		Each vial contains: Ceftazidime….250mg		Rs. 15000/-	of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017.The evidence of submission of renewal of year 2020 is not submitted by the firm.					
91.	047045	Telexil 500mg Capsule Each capsule contains: Cefadroxil as monohydrate….500mg	05-09-2007	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2012 and 2017 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The renewal application for year 2022 was due on 04.09.2022 but submitted after due date.					
92.	053277	Amoxicillin 500mg Capsule Each capsule contains: Amoxicillin as Trihydrate….500mg (BP Specifications)	02-12-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted by the firm further section approval letter for penicillin is also not submitted by the firm					
93.	053274	Amoxicillin 125mg/5ml Suspension Each 5ml contains: Amoxicillin as Trihydrate….125mg (BP Specifications)	02-12-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks:					

Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted by the firm further section approval letter for penicillin is also not submitted by the firm					
94.	067303	Flucotiech 150mg Capsule Each capsule contains: Fluconazole….150mg (BP Specifications)	28-12-2010	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter No. F.1-65/2018-RRR dated 26.01.2023. However, no evidence has been submitted in this regard.					
95.	048671	Lincofanc 500mg Capsule Each capsule contains: Lincomycin as HCl…..500mg (Manufacturer Specifications)	15-07-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter No. F.1-65/2018-RRR dated 26.01.2023. The firm informed on dated 21.02.2023 (Dy.No.5027-R&I) that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
96.	047053	C- Pera 250mg Dry Powder Injection Each vial contains: Cefoperazone Sodium…..250mg (USP Specifications)	05-09-2007	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2012 and 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal application for year 2022 was due on 04.09.2022 but submitted after due date.					
97.	015895	Dexone 1ml Ampoule Injection Each ml contains: Dexamethasone sodium phosphate eq. to Dexamethasone…..4mg	14-09-1994 Transfer of Reg: **22-07-2005**	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug

					Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted. Section approval letter for injectable steroid is also not submitted by the firm.					
98.	045264	Revox 250mg Tablet Each Tablet contains: Levofloxacin…..250mg (Ep. Specifications)	**21-03-2007** Change of BN: 21.07.2009	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 135000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after nine months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2012 and 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017.The renewal application for year 2022 was due on 04.09.2022 but submitted after due date.					
99.	045265	Revox 500mg Tablet Each Tablet contains: Levofloxacin…..500mg (Ep. Specifications)	**21-03-2007** Change of BN: 21.07.2009	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 135000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after nine months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
100.	047478	U-Gravi 50mg/ml Injection Each ml contains: Dimenhydrate…50mg (Manufacturer Specifications)	24-01-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug

					Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
101.	047467	Lumisnag 20/120mg Tablet Each Tablet contains: Artemether….20mg, Lumefantrine….120mg (Manufacturer Specifications)	24-01-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2013 & 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017.The evidence of submission of renewal of year 2018 is not submitted.					
102.	048665	Uni- Pine 30mg Tablet Each Tablet contains: Nimodipine…...30mg (BP Specifications)	15-07-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2013 & 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017.The evidence of submission of renewal of year 2018 is not submitted.					
103.	003909-EX	Livogale 250mg Tablet Each Tablet contains: Levofloxacin…250mg	18-12-2012	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 15000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted within sixty days of after due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within sixty days.					
104.	047061	Bon- Tech 0.5mcg Tablet	05-09-2007	Dy. No. 35225	Deferred for submission of fee (Rs. 45000/) under SRO

		Each Tablet contains: Alfacalcidol…0.5mcg (USP Specifications)		dated 05.12.2022 Rs. 15000/-	1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2012 and 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within one year.					
105.	047060	U-Plat 75mg Tablet Each Tablet contains: Clopidogrel as bisulphate….75mg (USP Specifications)	05-09-2007	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2012 and 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within one year.					
106.	067302	Uni- Zide 25mg Tablet Each Tablet contains: Hydrochlorothiazide…. 25mg (BP Specifications)	28-12-2010	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017.The evidence of submission of renewal of year 2020 is not submitted.					
107.	47051	U-Gyl 500mg/100ml Infusion Each 100 ml contains: Metronidazole…….. 500mg	05-09-2007	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three

		(BP Specifications)			months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within sixty days					
108.	047047	Flo-Tech 200mg/100ml Injection Each 100 ml contains: Ofloxacin…..200mg (USP Specifications)	05-09-2007	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within sixty days					
109.	048655	Pyriclo Tablet Each Tablet contains: Meclozine HCl….25mg, Pyridoxine HCl….50mg (USP Specifications)	15-07-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
110.	067301	U- Losapot 50mg Tablet Each tablet contains: Losartan Potassium….50mg (USP Specifications)	28-12-2010	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020

					under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
111.	000960-EX	U- Viagra 50mg Tablet Each Tablet contains: Sildenafil as citrate…..50mg	10-05-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
112.	048666	Montbliss 4mg Tablet Each Chewable Tablet contains: Montelukast sodium eq. to Montelukast ….4mg (Manufacturer Specifications)	15-07-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
113.	067299	Unibesylate 5mg Tablet Each Tablet contains: Amlodipine as besylate…..5mg (BP Specifications)	28-12-2010	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
114.	067300	Unibesylate 10mg Tablet Each Tablet contains: Amlodipine as besylate…..10mg (BP Specifications)	28-12-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks:					

Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
115.	047064	Montbliss 5mg Tablet Each Chewable Tablet contains: Montelukast sodium eq. to Montelukast ….5mg (Manufacturer Specifications)	05-09-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
116.	047062	U- Glim 2mg Tablet Each Tablet contains: Glimperide…..2mg (USP Specifications)	05-09-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within sixty days					
117.	067310	Zemtiech 30mg Tablet Each tablet contains: Diltiazem…...30mg (BP Specifications)	28-12-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks:					

Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is still pending.					
118.	003910-EX	Livogale 500mg Tablet Each Tablet contains: Levofloxacin….500mg	18-12-2012	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for input as per status in 279th meeting of Registration Board and then consideration under SRO 1005(I)/2017.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within sixty days					
119.	000677-EX	U-Slim 37.5mg each Tablet contains: Phentermine hydrochloride…37.5mg	14-06-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 90000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after due date but within one year. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017.					
120.	061260	Unidrine 30mg Tablet Each tablet contains: Ephedrine HCl…...30mg (Manufacturer Specifications)	07-04-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
121.	015893	Unimethazine Injection Each ml contains: Cyanocobalamin…… 1000 mg	14-09-1994 Transfer of Reg: Dt: **22-07-2005**	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks:					

Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
122.	048656	Bon- Tech 0.25mcg Tablet Each Tablet contains: Alfacalcidol…0.25mcg (USP Specifications)	15-07-2008	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
123.	047059	U- Gran 45mg Tablet Each Tablet contains: Pioglitazone….45mg (USP Specifications)	05-09-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within one year					
124.	048654	U- Gran 15mg Tablet each Tablet contains: Pioglitazone….15mg (USP Specifications)	15-07-2008	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted.					
125.	067295	Muskodine 2mg Tablet Each tablet contains: Tizanidine…..2mg (USP Specifications)	28-12-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug

					Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
126.	047056	Azogrip 250mg Tablet Each Tablet contains: Azithromycin….250mg (USP Specifications)	05-09-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within one year					
127.	061046	Unizem 10mg Tablet Each Tablet contains: Diazepam…….10mg (USP Specifications)	11-04-2009	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2014 and 2019 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2019 is not submitted.					
128.	047063	U-Glim 4mg Tablet each Tablet contains: Glimepiride…...4mg (USP Specifications)	05-09-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be

					referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within one year					
129.	015890	Unimethazone Injection Each ml contains: Promethazine….2mg	14-09-1994 Transfer of Reg: **22-07-2005**	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2015 and 2020 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2020 is not submitted.					
130.	047046	Revox 500mg/100ml Injection Each 100ml contains: Levofloxacin (as Hemihydrate) …….500mg (Ep. Specifications)	05-09-2007	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Deferred for submission of fee (Rs. 45000/) under SRO 1005(I)/2017 for year 2022 as renewal application was submitted after three months of due date. After submission of fee the case shall be placed before Registration Board for consideration of regularization of renewals for previous & current submission under the aforesaid SRO. Meanwhile the case shall also be referred to concerned section for input as per status in 279th meeting of Registration Board.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2017 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The renewal for year 2022 has been submitted after due date but within one year. Approval of change of BN is required.					
131.	053276	Amoxicillin 250mg Capsule Each capsule contains: Amoxicillin…...250mg (BP Specifications)	02-12-2008	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
Remarks: Firm was advised to submit evidence of submission of renewal application for year 2013 and 2018 vide letter dated 26.01.2023. The firm has now informed that they have submitted application with 30000/- fee on 04.12.2017. The evidence of submission of renewal of year 2018 is not submitted. Section approval letter is also not submitted.					

Case No.5 Renewal applications submitted under SRO 1005(I)/2017.

The firm has informed that below mentioned application for renewal of Drugs under SRO 1005(I)/2017 dated 28th November, 2017 are yet to be considered. The firm further informed that majority of products applied were included in the 281st DRB meeting and renewal letter was issued but following products were not included in the agenda of meeting and hence renewal was not granted. Details are as under:

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad					
1.	025657	M-Butamol Tablets Each tablet contains: Salbutamol BP……..4mg	30.03.2000 PRV: **09.06.2005**	Rs.30000/- dated 29.11.2017 Dy. No. 12524 dated 03.06.2020 Rs. 10000	Registration Board regularized the renewal of year 2010 and 2015 under SRO 1005(I)/2017 and further granted renewal w.e.f 09.06.2020 to 05.06.2025 The firm shall apply for correction in salt form (Salbutamol sulphate) and specifications as per decision of 295th meeting of Registration Board
Remarks: The product was deferred in 323rd meeting of Registration Board for submission of evidence of renewal of year 2010 for consideration under SRO 1005(I)/2017. Hence in the reply the firm informed that due date of application was 08.06.2010 hence its falls under SRO 1005(I)/2017.					
2.	021613	Irosul Tablet 200mg Each tablet contains: Ferrous Sulphate USP…..200mg	20.05.1998	Rs.30000/- dated 29.11.2017 Rs. 10000/- dated 11.05.2018	Registration Board regularized the renewal of year 2013 under SRO 1005(I)/2017 and further granted renewal w.e.f 20.05.2018 to 19.05.2023 The firm shall submit reference of specifications as per decision of 295th meeting of Registration Board.
Remarks: The product was deferred in 323rd meeting of Registration Board for submission of following: i. Approval of transfer for registration from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad ii. Evidence of submission of renewal for year 2008. In reply the firm submitted a copy of letter for transfer of registration of Irosul Tablet 200mg in name of new title dated 15.05.2008 with 8000/- fee.					
3.	025581	Amchoram-4 Tablet Each tablet contains: Chlorpheniramine Maleate BP……4mg	08.03.2000 PRV: **09.06.2000**	Rs.30000/- dated 29.11.2017 Dy. No. 12524 dated 03.06.2020 Rs. 10000	Registration Board regularized the renewal of year 2010 and 2015 under SRO 1005(I)/2017 and further granted renewal w.e.f 09.06.2020 to 05.06.2025 The firm shall submit reference of specifications as per decision of 295th meeting of Registration Board
Remarks:					

The product was deferred in 323rd meeting of Registration Board for submission of following: i. Approval of transfer for registration from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad ii. Evidence of submission of renewal for year 2010. In the reply the firm informed that due date of application was 08.06.2010 hence its falls under SRO 1005(I)/2017, further copy of approval of transfer of registration has also been submitted from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad dated 09.06.2005.					
4.	021780	Amfer Tablet Each tablet contains Ferrous Fumarate USP……200mg	20.05.1998	Rs.30000/- dated 29.11.2017 Rs. 10000/- dated 11.05.2018	Registration Board regularized the renewal of year 2013 under SRO 1005(I)/2017 and further granted renewal w.e.f 20.05.2018 to 19.05.2023 The firm shall submit reference of specifications as per decision of 295th meeting of registration Board.
Remarks: The product was deferred in 323rd meeting of Registration Board for submission of following: i. Approval of transfer for registration from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad ii. Evidence of submission of renewal for year 2008. In reply the firm submitted a copy of letter for transfer of registration of Irosul Tablet 200mg in name of new title dated 15.05.2008 with 8000/- fee.					

Case No. 6 Renewal application of DNL40mg Injection (085358) applied by M/s Horizon Healthcare Pvt Limited PSIE Taxila.

PR Section has informed that M/s M/s Horizon Healthcare Pvt Limited PSIE Taxila has informed that the firm has applied for transfer of registration of subject mentioned product in name of new title i.e. M/s Horizon Healthcare Pvt Limited 35-A Punjab Small Industrial Estate Taxila Formerly M/s Walt Danzay Pharmaceuticals 35-A Punjab Small Industrial Estate Taxila approved vide Licensing Division Letter No. F.1-17/2012-Lic dated 06.07.2018. The section has requested to confirm the renewal of registration of subject mentioned drug.

Reg. No.	Product Name & Composition	Date of Reg.	Renewal application submission details	Remarks
085358	DNL 40mg Injection Each vial contains: Omeprazole as sodium ….40mg As per Innovator's Specifications)	17.10.2017	Dy. No. 2869 dated 31.01.2023 Rs. 45000/- vide slip No. 747609350891	

The firm has submitted the requisite fee as required under SRO 1005(I)/2017.

Decision: Registration Board approved the change in title from M/s Walt Danzay Pharmaceuticals 35-A Punjab Small Industrial Estate Taxila to M/s Horizon Healthcare Pvt Limited 35-A Punjab Small Industrial Estate Taxila for DNL 40mg Injection (085358) as per Licensing Division approval vide Letter No. F.1-17/2012-Lic dated 06.07.2018. Registration Board further regularized the renewal for year 2022 under SRO 1005(I)/2017 and granted renewal w.e.f 17.10.2022 to 16.10.2027.

Case No: 7 Renewal applications of Aulton Pharmaceuticals Plot No. 84/1, Block –A Phase 5 Industrial Estate Hattar

PR section has referred an application for regularization of renewal of registration of Aultocip Tablets 250 & 500mg registered in name of M/s Aulton Pharmaceuticals Plot No. 84/1, Block –A Phase 5 Industrial Estate Hattar. While scrutiny it was observed that renewal application of the 27 products including the aforesaid ones were submitted after due date but within sixty. Accordingly, the firm was advised to submit the differential fee which has been submitted as per details mentioned against each:

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
1.	080555	Alta D Injection IM Each 1ml amber glass ampoule contains: Cholecalciferol… 5mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	The firm has informed that they have submitted renewal application on 03.05.2021 on the due date 01.05.2021 & 02.05.2021 was Saturday and Sunday.
2.	080556	Altum Injection IM Each 1ml amber glass ampoule contains:- Artemether… 80mg Oily Solution for Injection (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
3.	080557	Cyno 12 Injection IM/IV Each 1ml amber glass ampoule contains: Mecobalamin… 500mcg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
4.	080558	Ferrix Injection Each 5ml amber glass ampoule contains: Iron Sucrose Complex eq. to Elemental Iron … 100mg (BP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
5.	080559	N90 Injection IV Each 5ml amber glass ampoule contains: Sodium Chloride… 45mg (BP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
6.	080560	Orkit Injection IV Each 1ml amber glass ampoule contains: Ketorolac Tromethamine… 30mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
7.	080561	W Inject Water for Injection IV Each 5ml amber glass ampoule contains: Water for Injection (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
8.	080563	Mydexa Ophthalmic Solution	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-

		Each ml contains:- Tobramycin … 3mg Dexamethasone… 1mg (USP Specifications)			
9.	080564	Aultocip D Eye Drops Each ml contains: Ciprofloxacin HCl eq. to Ciprofloxacin …. 3mg Dexamethasone…. 1mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
10.	080565	Selmoxi Ophthalmic Solution Each ml contains: Moxifloxacin HCl eq. to Moxifloxacin … 5mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
11.	080566	Cylic Ointment Each gram contains: Betamethasone Dipropionate… 9.6mg (0.0064%) eq. to Betamethasone… 0.05% Salicylic Acid…. 450mg (3%) (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
12.	080567	Altazole 10% Each gram contains: Clotrimazole… 100mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
13.	080568	Tica Ointment 0.005% Each gram contains: Fluticasone Propionate… 0.05mg (50mcg) (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
14.	080569	Tica Cream 0.005% Each gram contains: Fluticasone Propionate… 0.05mg (50mcg) (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
15.	080570	Remep Injection 40mg IV Each vial contains:- Esomeprazole Sodium powder eq. to Esomeprazole… 40mg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
16.	080572	Cokast Sachet 4mg Each sachet contains: Montelukast Sodium eq. to Montelukast… 4mg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
17.	080573	Cyno-12 Tablet Each film coated tablet contains: Mecobalamin J.P… 500mcg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-

18.	080574	Altadine Tablet 5mg Each film coated tablet contains: Desloratidine… 5mg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
19.	080575	Aultocip Tablet 250mg Each film coated tablet contains: Ciprofloxacin HCl H2O 291.5mg eq. to Ciprofloxacin …. 250mg (BP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
20.	080576	Aultocip Tablet 500mg Each film coated tablet contains: Ciprofloxacin HCl . H2O 583mg eq. to Ciprofloxacin …. 500mg (BP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
21.	080577	Valence Tablet 250mg Each film coated tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin … 250mg (BP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
22.	080578	Valence Tablet 500mg Each film coated tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin … 500mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
23.	080579	Altocam B Tablet 20mg Each uncoated tablet contains: Piroxicam Beta Cyclodextrin eq. to Piroxicam… 20mg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
24.	080580	Aultotrim Tablet 100mg Each vaginal tablet contains: Clotrimazole… 100mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
25.	080582	Brobal Capsule 75mg Each hard gelatin capsule contains: Pregabalin … 75mg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
26.	080583	Brobal Capsule 150mg Each hard gelatin capsule contains: Pregabalin … 150mg (Manufacturer Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
27.	080585	Aulta Z Capsule 250mg Each hard gelatin capsule contains: Azithromycin Dihydrate eq. to Azithromycin … 250mg (USP Specifications)	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-

28.	080586	Aulta Z Dry Suspension 200mg Each 5ml of reconstituted suspension contains: Azithromycin Dihydrate eq. to Azithromycin … 200mg	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
29.	080587	Dakra Capsule 20mg Each hard gelatin capsule contains: Omeprazole Sodium enteric coated pellets 8.5% w/w eq. to Omeprazole… 20mg	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
30.	080588	Dakra Capsule 40mg Each hard gelatin capsule contains: Omeprazole Sodium enteric coated pellets 8.5% w/w eq. to Omeprazole… 40mg	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
31.	080589	Remep Capsule 20mg Capsule Each hard gelatin capsule contains: Esomeprazole Sodium enteric coated pellets 22.5% w/w eq. to Esomeprazole… 20mg	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-
32.	080590	Remep Capsule 40mg Capsule Each hard gelatin capsule contains:- Esomeprazole Sodium enteric coated pellets 22.5% w/w eq. to Esomeprazole… 40mg	03-05-2016	Dy. No 12923 dated 03.05.2021 Rs. 10000/-	-do-

Decision: **Keeping in view the stance of the firm as narrated in last column above that on the due date (02.05.2021) was Sunday i.e. official holiday. Hence the above renewal applications are considered to be submitted within time as required under Rule 27 of Drug (LR&A) Rules 1976.**

Case No: 8 Renewal applications of Sarco Chemicals Industries, 17-Km, Lahore Road, Multan

Below mentioned products were cancelled in 312th meeting of Registration Board as renewal applied after prescribed time period for year 2014 i.e. after expiry of 60 days and accordingly letter of cancellation was issued on 09.12.2021.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
1.	021674	Lugol's Iodine Lotion Iodine…5%w/v Pot Iodide …10%w/v	20-05-1998	Dy. No. 425-B dated: 12.03.2019 Rs. 10000/-	
2.	029748	Sarodin Solution Povidone Iodine eq. to 1% of available Iodine W/V	26.02.2003	Dy. No. 425-B dated: 12.03.2019 Rs. 10000/- Rs. 15000/-	

				Dy No.1925 Dated 19.01.2023	

The firm has informed that they have submitted following fee in 2008:

i. Copy of challan of fee for renewal (Rs.4000/-) for Lugol's Iodine Lotion (Reg No.021674) dated 22.04.2008
ii. Copy of challan of fee for transfer (Rs.8000/-) for Lugol's Iodine Lotion (Reg No.021674) dated 23.01.2008
iii. Copy of challan of fee for renewal (Rs.4000/-) for Sarodin Solution (Reg No. 029748) dated 23.01.2008
iv. Copy of challan of fee for transfer (Rs.8000/-) for Sarodin Solution (Reg No. 029748) dated 23.01.2008

The above submissions have been attested by District Account officer Multan. Submitted please.

Decision: Registration Board has already decided the matter and the decision of the board has been communicated accordingly.

Item No. III Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A.	Imported Human Biologicals from Reference Countries	3
B.	Imported Human Biologicals from Non-Reference Countries	4
C.	Imported Veterinary Biologicals from Reference Countries	2
D.	Imported Veterinary Biologicals from Non-Reference Countries	4
E.	Miscellaneous/ Deferred Cases	8
Total		21

Sr. No.	Assistant Director	Designated No.	No. of Cases
1.	Mr. M. Kashif	DD-I	6
2.	Mr. Hafiz Ahsan	DD-II	8
3.	Ms. Haleema Shareef	DD-III	7

CASES OF DD-I (MR. MUHAMMAD KASHIF)

CANCELLATION OF REGISTRATION OF IMPORTED DRUGS

M/s Roche Pakistan Ltd, 37-B, 1st Floor Block-6 PECHS, Karachi has submitted request for cancellation of registration of imported drug as per following details.

Sr. no.	Product Name	Reg. No.	Reason for De-Reg. (Stated by Firm)	Alternative Registered Products
1.	Ropegra Each dose of 1 ml contains: 180 mcg of Peginterferon alfa-2a	077512	1- This decision has been made by our Principal F.Hoffmann-La Roche, Basel Ltd, as they have discontinued the product and no more manufacturing it. 2- The treatment paradigm of Hepatitis has been shifted towards the modern alternative oral therapies which are more advanced and effective and are available in the market, therefore the	PEG – INF by Ferozsons Laboratories Taget by Hilton Pharma Pvt.Ltd. Unipeg by Getz Pharma Pvt.Ltd.

			product is no longer drug of choice.	

SOP Requirement Firms Response	Documents Submitted by the Firms
Application.	Application with a fee Rs.7, 500/- is submitted.
Copy of registration letter.	Submitted
Justification.	Submitted
List of alternatives brands/ FPPs available in the country.	Submitted
An undertaking that: No case is pending at any forum / court of law Regarding this product. Provided information/ documents are true/ correct.	Submitted

Decision: Registration Board after discussion on the matter decided to call the management of the firm for personal hearing under section 42 of the Drugs Act, 1976 of schedule VI of DRAP Act 2012 before cancellation of the product.

CANCELLATION OF REGISTRATION

M/s Sanofi-Aventis Pakistan limited. Plot No. 23, Sector 22, Korangi Industrial Area, Karachi has submitted request for cancellation of registration/withdrawal of registration application of imported products as per following details:

Sr. No	Product name	Reg. No	Reason of license/registration application withdrawal stated by firm	Alternative registered products
2.	Vaxigrip	025266	Production of Vaxigrip was discontinued after NH 2020-2021 Influenza Season. Sanofi Pasteur has completed switch of Trivalent Influenza Vaccine production to Quadrivalent Influenza Vaccine. Quadrivalent Influenza Vaccine namely VAXIGRIP TETRA is already registered vide registration #: 105066 dated 7th October 2020 in Pakistan which includes two A strains and two B strains corresponding to both of the B lineages and same has been launched and is available in the market. The switch will allow broader protection against Influenza Virus strains. It will also enable to rationalize production capacities and optimize Influenza vaccine supply in context of high global demand increase.	Vaxigrip Tetra – Sanofi-Aventis Pakistan Limited
3.	Dengvaxia, Powder for Suspension for Injection with NaCl Solution 0.4%	082506 (Powder) 082509 (Solvent)	Sanofi Pasteur, France (manufacturer of subjected vaccines) has informed that they would like to withdraw the license of these vaccines, this decision is purely based on commercial reason and is not related to safety, quality or efficacy of the vaccines.	-
4.	Dengvaxia MD, Powder for Suspension for Injection with NaCl Solution 0.9%	082507 (Powder) 082510 (Solvent)		-
5.	Pentaxim	045699	*Sanofi has decided to withdraw the license of Pentaxim vaccine*, this decision is not based on any quality, safety or efficacy	Hexaxim - Sanofi-Aventis

			issues but has been taken for the following reason: Hexaxim vaccine which is already registered under the name of sanofi-aventis Pakistan limited bearing Reg No. 079275 is the only fully liquid, ready to use 6-in-1 vaccine to protect infants against diphtheria, tetanus, pertussis (whooping cough), Hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type B. *A 6 in 1 pediatric vaccine reduces the number of vaccination visits for infants as compared to Pentaxim and an additional advantage of HepB antigen which is in high prevalence in Pakistan* that is available in Hexaxim. It is more convenient for parents to complete the recommended vaccination schedule and thus provide better protection to their children prone to 6 major diseases during childhood. It is also preferable to use 6 in 1 vaccine (Hexaxim) rather than 5 in 1 vaccine (Pentaxim) to avoid more visits and to improve the vaccination coverage rate.	Pakistan Limited

SOP Requirement	**Firm Response**
Application	Application on company letter head
Copy of registration letter and last renewal status	Registration letter and last renewal status provided for registered products Initial registration application provided for under registration products
Justification	Provided
List of alternative brands/FPPs available in country	Provided for Vaxigrip and Pentaxim
An undertaking that: 1. No case is pending at any forum/court of law regarding this product 2. Provided information/documents are true/correct	Provided

Decision: Registration Board after discussion on the matter decided to call the management of the firm for personal hearing under section 42 of the Drugs Act, 1976 of schedule VI of DRAP Act 2012 before cancellation of the above said products.

CASES OF DD-II (MR. HAFIZ MUHAMMAD AHSAN)

Imported Human Biological product from Reference countries:

6.	Name, address of Applicant / Importer	M/s Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi.
	Details of Drug Sale License of importer	**License No:** 0267 **Address:** Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. **Address of Godown:** • R-PI, plot no. 116, sector 15, K.I.A, Karachi • R-PI, plot no. 56, sector 15, K.I.A, Karachi **Validity:** 13-09-2024. **Status:** Drug License by way of wholesale and Drug License by way of retail sale **Renewal:** N/A

	Name and address of marketing authorization holder (abroad)	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany.
	Name, address of manufacturer(s)	Genentech Inc., 1 DNA Way, South San Francisco, CA 94080, USA.
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	EMA eCPP Certificate: 09/22/172400 Issue on 04/07/2022.
	Details of letter of authorization / sole agency agreement	• Authorization letter from M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 27-09-2022. • Copy of relationship letter indicating relation of all Roche companies with M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.29311 dated 17-10-2022
	Details of fee submitted	**Deposit Slip no**. 1770410768 **PKR** 75,000: **Dated** 20-09-2022
	The proposed proprietary name / brand name	**Lunsumio**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**API**: Mosunetuzumab **Strength** : **1 mg** Concentration per vial: 1mg/2ml
	Dosage form of applied drug	Intravenous Use
	Pharmacotherapeutic Group of (API)	Monoclonal Antibodies (ATC code: L01XC)
	Reference to Finished product specifications	Innovator's specifications
	Proposed pack size	1's vial
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	2°C - 8°C
	The status in reference regulatory authorities	Lunsumio 1mg concentrate for solution for infusion glass vial (EMA Approved)
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Genentech, Inc.1 DNA Way South San Francisco, California 94080 USA.
	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)	• 48 months real time stability data at -20°C of 03 batches • 06 month accelerated stability data 5°C of 03 batches
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	2 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 5°C of 03 batches • 06 month accelerated stability data 25°C of 03 batches
	Module-IV Non-Clinical	**4.2.1 Pharmacology** **4.2.1.1 Primary Pharmacodynamics** • 22-0083: In Vitro Biological Characterization of Mosunetuzumab for Human C1q Binding Activity • In Vitro Comparison of BTCT4465A Produced from E. coli and CHO Cells in B-Cell Killing, T-Cell Activation, and Cytokine Production With Human PBMCs • In Vitro Evaluation of BTCT4465A for Human Fc Gamma Receptor Binding Activities • Characterization of Anti-CD20/CD3 TDB Antibody Mechanism of Action and Efficacy • Comparison of Biological Activity (B-Cell Killing, T-Cell Activation, and Cytokine Production) of POC Anti-CD20/CD3 TDB Antibody and BTCT4465A with Human and Cyno Peripheral Blood Mononuclear Cells • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Rituximab-DANA • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Dexamethasone

		• In Vitro Evaluation of BTCT4465A (Anti-CD20/CD3 TDB) v0.1 and BTCT4465A v0.2 for Binding Activity to Human and Cynomolgus Monkey B Cells and T Cells • A Single-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody and Non-CD20-Binding TDB Antibody in Human CD20/CD3 Double-Transgenic Mice • Dose Titration of Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in Depleting Endogenous B Cells in Human CD20/CD3 Double-Transgenic (TG) Mice • A Single Dose, Time-Course Efficacy Study with Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in huCD20/CD3 Double Transgenic Mice • A Repeat-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody in Humanized NSG Mice **4.2.2 Pharmacokinetics** **4.2.2.1 Analytical Methods and Validation Reports** (if separate reports are available) • The Validation History of an ELISA Method for the Quantitation of BTCT4465A (Mosunetuzumab) in Cynomolgus Monkey Serum • The Validation History of an Immunoassay Method for Detection of Antibodies to BTCT4465A (Anti-CD20/CD3 TDB) in Cynomolgus Monkey Serum **4.2.2.7 Other Pharmacokinetic Studies** • Pharmacokinetics and Pharmacodynamics of E. coli- or CHO-Produced Anti-CD20/CD3 TDB Antibody in huCD20/huCD3 Transgenic Mice • A Single Dose Pharmacokinetic and Pharmacodynamic Study of BTCT4465A Administered by Intravenous Injection to Male Cynomolgus Monkeys • A Single Dose Pharmacokinetic Comparability Study of BTCT4465A via Intravenous Administration to Male • Cynomolgus Monkeys with a 11-Day Observation Period **4.2.3 Toxicology** **4.2.3.1 Single-Dose Toxicity (in order by species, by route)** • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Directed Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of

		BTCT4465A via Intravenous Infusion or Subcutaneous Administration in Cynomolgus Monkeys with a 7-week Recovery Period **4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 T-cell Dependent Bispecific Antibody Administered by Intravenous Injection to Cynomolgus Monkeys**.** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 with or without steroid or Rituximab pretreatment via Intravenous or Subcutaneous Administration in Male Cynomolgus Monkeys • Pilot 28-Day Repeat Dose Intravenous Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody using Magnetic Resonance Imaging in the Cynomolgus Monkey • BTCT4465A: 25 Day Intravenous (Infusion) Administration Pilot Toxicity Study in the Monkey • BTCT4465A: 26 Week Multiple Dose Intravenous (Infusion) Administration Toxicity and Toxicokinetic Study in the Cynomolgus Monkey **4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.)** **4.2.3.5.2 Embryo-fetal development** • The Weight-of-Evidence Assessment of Developmental Effects for Mosunetuzumab - for nonUS submission. **4.2.3.7 Other Toxicity Studies (if available)** **4.2.3.7.7 Other** • Tissue Cross-reactivity of BTCT4465A with Human and Select Cynomolgus Monkey Tissues • In Vitro Characterization of the Biological Activities of BTCT4465A in Human PBMCs and the Impact of Low Percentage of Anti-CD3 Homodimers on BTCT4465A Activity
	Module-V Clinical	**Study Design: GO29781** • An open Label, Multicenter, Phase I/II dose escalation study and expansion study evaluating the Safety, efficacy and tolerability study and Pharmacokinetics of mosunetuzumab as a single agent (and in combination with Tecentriq) in patients with Relapsed or Refractory B Cell Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia. • 447 enrolled into mosunetuzumab IV montherap cohorts (Group A and Group B escalation + expansion).
Remarks of Evaluator:		

Sr. No.	Observations	Response by the Firm
1.	Observer blind, Phase-III clinical study data are required since submitted clinical trial is an open label, Phase I/II study design. Justification is required.	The firm has submitted that the application for registration of new drug, Lunsumio (mosunetuzumab) 1mg and 30mg concentrate for solution for infusion, is applied on the basis of phase I/II GO29781 study, and same is the basis of approval for this product in the reference regulatory authorities such as USFDA, EMA and Swissmedic. We would like to add that the phase III (CELESTIMO study) trials for this drug are in process as informed by our principal, F. Hoffmann-La Roche Ltd., Basel, Switzerland.
2.	Relationship of product license holder with Basel, Switzerland.	Product Specific Authorization letter has been issued by M/s. F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland & the marketing authorization holder is Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach- Wyhlen, Germany. For this purpose , the firm has submitted a copy of letter indicating relationships among Roch Group of Companies, wherein it has been mentioned M/s F.Hoffmann-La Roche Ltd., Basel Switzerland is the operational headquarter of the Roche Group.

<u>Decision:</u> Registration Board after due discussion decided to defer the case for further deliberation in the nest meeting.

7.	Name, address of Applicant / Importer	M/s Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi.
	Details of Drug Sale License of importer	**License No:** 0267 **Address:** Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. **Address of Godown:** • R-PI, plot no. 116, sector 15, K.I.A, Karachi • R-PI, plot no. 56, sector 15, K.I.A, Karachi **Validity:** 13-09-2024. **Status:** Drug License by way of wholesale and Drug License by way of retail sale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany
	Name, address of manufacturer(s)	Genentech Inc., 1 DNA Way, South San Francisco, CA 94080, USA.
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	EMA eCPP Certificate No: 05/22/172402 Issue on 04-07-2022
	Details of letter of authorization / sole agency agreement	• Authorization letter from M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 27-09-2022. • Copy of relationship letter indicating relation of all Roche companies with M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 29311 ; Dated 17-10-2022
	Details of fee submitted	**Deposit Slip no**. 43585097156 **PKR** 75,000: **Dated** 20-09-2022
	The proposed proprietary name / brand name	**Lunsumio**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**API**: Mosunetuzumab **Strength**: **30 mg** Concentration per vial: 30mg/30ml
	Dosage form of applied drug	Intravenous Use
	Pharmacotherapeutic Group of (API)	Monoclonal Antibodies (ATC code: L01XC)
	Reference to Finished product specifications	Innovator's specifications
	Proposed pack size	1's vial
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	2°C - 8°C
	The status in reference regulatory authorities	Lunsumio 30mg concentrate for solution for infusion glass vial (EMA Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Genentech, Inc.1 DNA Way South San Francisco, California 94080 USA.
	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)	• 48 months' real time stability data at -20°C of 03 batches • 06 month accelerated stability data 5°C of 03 batches
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of

		excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	50 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 24 months' real time stability data at 5°C of 03 batches • 06 month accelerated stability data 25°C of 03 batches
	Module-IV Non-Clinical	**4.2.1 Pharmacology** **4.2.1.2 Primary Pharmacodynamics** • 22-0083: In Vitro Biological Characterization of Mosunetuzumab for Human C1q Binding Activity • In Vitro Comparison of BTCT4465A Produced from E. coli and CHO Cells in B-Cell Killing, T-Cell Activation, and Cytokine Production With Human PBMCs • In Vitro Evaluation of BTCT4465A for Human Fc Gamma Receptor Binding Activities • Characterization of Anti-CD20/CD3 TDB Antibody Mechanism of Action and Efficacy • Comparison of Biological Activity (B-Cell Killing, T-Cell Activation, and Cytokine Production) of POC Anti-CD20/CD3 TDB Antibody and BTCT4465A with Human and Cyno Peripheral Blood Mononuclear Cells • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Rituximab-DANA • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Dexamethasone • In Vitro Evaluation of BTCT4465A (Anti-CD20/CD3 TDB) v0.1 and BTCT4465A v0.2 for Binding Activity to Human and Cynomolgus Monkey B Cells and T Cells • A Single-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody and Non-CD20-Binding TDB Antibody in Human CD20/CD3 Double-Transgenic Mice • Dose Titration of Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in Depleting Endogenous B Cells in Human CD20/CD3 Double-Transgenic (TG) Mice • A Single Dose, Time-Course Efficacy Study with Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in huCD20/CD3 Double Transgenic Mice

		• A Repeat-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody in Humanized NSG Mice **4.2.2 Pharmacokinetics** **4.2.2.1 Analytical Methods and Validation Reports** (if separate reports are available) • The Validation History of an ELISA Method for the Quantitation of BTCT4465A (Mosunetuzumab) in Cynomolgus Monkey Serum • The Validation History of an Immunoassay Method for Detection of Antibodies to BTCT4465A (Anti-CD20/CD3 TDB) in Cynomolgus Monkey Serum **4.2.2.8 Other Pharmacokinetic Studies** • Pharmacokinetics and Pharmacodynamics of E. coli- or CHO-Produced Anti-CD20/CD3 TDB Antibody in huCD20/huCD3 Transgenic Mice • A Single Dose Pharmacokinetic and Pharmacodynamic Study of BTCT4465A Administered by Intravenous Injection to Male Cynomolgus Monkeys • A Single Dose Pharmacokinetic Comparability Study of BTCT4465A via Intravenous Administration to Male Cynomolgus Monkeys with a 11-Day Observation Period **4.2.3 Toxicology** **4.2.3.1 Single-Dose Toxicity (in order by species, by route)** • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Directed Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of BTCT4465A via Intravenous Infusion or Subcutaneous Administration in Cynomolgus Monkeys with a 7-week Recovery Period **4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 T-cell Dependent Bispecific Antibody Administered by Intravenous Injection to Cynomolgus Monkeys**.** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 with or without steroid or Rituximab pretreatment via Intravenous or Subcutaneous Administration in Male Cynomolgus Monkeys

		• Pilot 28-Day Repeat Dose Intravenous Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody using Magnetic Resonance Imaging in the Cynomolgus Monkey • BTCT4465A: 25 Day Intravenous (Infusion) Administration Pilot Toxicity Study in the Monkey • BTCT4465A: 26 Week Multiple Dose Intravenous (Infusion) Administration Toxicity and Toxicokinetic Study in the Cynomolgus Monkey **4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.)** **4.2.3.5.2 Embryo-fetal development** • The Weight-of-Evidence Assessment of Developmental Effects for Mosunetuzumab - for nonUS submission. **4.2.3.7 Other Toxicity Studies (if available)** **4.2.3.7.7 Other** • Tissue Cross-reactivity of BTCT4465A with Human and Select Cynomolgus Monkey Tissues • In Vitro Characterization of the Biological Activities of BTCT4465A in Human PBMCs and the Impact of Low Percentage of Anti-CD3 Homodimers on BTCT4465A Activity
	Module-V Clinical	**Study Design: GO29781** • An Open Label, Multicenter, Phase I/II dose escalation study and expansion study evaluating the Safety, efficacy and tolerability study and Pharmacokinetics of mosunetuzumab as a single agent (and in combination with Tecentriq) in patients with Relapsed or Refractory B Cell Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia. • 447 enrolled into mosunetuzumab IV monotherapy cohorts (Group A and Group B escalation + expansion).

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
3.	Observer blind, Phase-III clinical study data are required since submitted clinical trial is an open label, Phase I/II study design. Justification is required.	The firm has submitted that the application for registration of new drug, Lunsumio (mosunetuzumab) 1mg and 30mg concentrate for solution for infusion, is applied on the basis of phase I/II GO29781 study, and same is the basis of approval for this product in the reference regulatory authorities such as USFDA, EMA and Swissmedic. We would like to add that the phase III (CELESTIMO study) trials for this drug are in process as informed by our principal, F. Hoffmann-La Roche Ltd., Basel, Switzerland.
4.	Relationship of product license holder with Basel, Switzerland.	Product Specific Authorization letter has been issued by M/s. F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland & the marketing authorization holder is Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach- Wyhlen, Germany. For this purpose , the

		firm has submitted a copy of letter indicating relationships among Roch Group of Companies, wherein it has been mentioned M/s F.Hoffmann-La Roche Ltd., Basel Switzerland is the operational headquarter of the Roche Group.

Decision: Registration Board after due deliberation decided to defer the case for further deliberation in the next meeting.

Imported Human Biological product from Non-reference countries:

8.	Name, address of Applicant / Importer	M/s Galaxy Pharma (Pvt.) Ltd. Address: Plot no. 28-C, Lane no. 09, Ittehad commercial Phase VI, DHA, Karachi-75500 Pakistan.
	Details of Drug Sale License of importer	M/s Galaxy Pharma (Pvt.) Ltd. Address: Plot no. 28-C, Lane no. 09, Ittehad commercial Phase VI, DHA, Karachi-75500 Pakistan. License No.: 124 Valid till: 02.09.2023
	Name and address of marketing authorization holder (abroad)	Name: Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR". Address: 5, Zroshuvalna str, Kyiv, Ukraine, 02099
	Name, address of manufacturer(s)	Name: Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR". Address: 5, Zroshuvalna str, Kyiv, Ukraine, 02099
	Name of exporting country	Ukraine.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The Firm has submitted original legalized CoPP certificate (CPP/UA/274/19/4) remains valid until unlimited issued by State Service of Ukraine on Medicine and Drugs Control for HUMODAR B 100R, suspension for injection 100IU/mL (1 mL of suspension which contains: 100IU insulin human recombinant (100% of crystalline protamine insulin). The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every three years.
		DML: Firm has submitted Original Legalized Drug Manufacturing Licence of manufacturer (Series AB License No. 598072) issued by State Service of Ukraine on Medicine and Drugs Control. The certificate is issued on January 17,2014
		GMP: Firm has submitted Original legalized GMP Compliance No. 062/2019/GMP Drug Manufacturing Licence of manufacturer (Series AB License No. 598072) issued by State Service of Ukraine on Medicine and Drugs Control. The certificate is issued on January 17,2014
	Details of letter of authorization / sole agency agreement	Firm has submitted a copy of power of attorney from Chairman of board of Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR". According to the letter, the firm Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR authorizes "Galaxy Pharma (Pvt.) Ltd. Plot no. 28-C, Lane no. 09, Ittehad commercial Phase VI, DHA, Karachi-75500 Pakistan with its place of business at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan as their business representative with undisputed powers authorized to deal with the product registration of Basagine, Insulin Glargine Injection (3 mL: 300 IU / Cartridge) in Pakistan as per mutually agreed terms and conditions by both companies. The letter was issued on August 26th, 2020.

		Further, firm has submitted sole agency Agreement between Getz Pharma (Pvt.) Limited and Gan & Lee Pharmaceuticals issued on October 23, 2020 valid for 05 years from date of issue.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy. No. 27646; Dated 19-10-2020
	Details of fee submitted	**Pack size**: - 3 ml in cartridge, 5 cartridges in package **Slip no.**: (Rs. 100,030/-) Slip No. 1979382 **Date**: 02-10-2020
	The proposed proprietary name / brand name	**HUMODAR B 100R, suspension for injections, 100 IU/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Insulin human (r-DNA) ……..... 100 IU/ml. Synonym of the applied drug - Isophane insulin
	Pharmaceutical form of applied drug	HUMODAR B 100R, suspension for injection in a vial or cartridge, a sterile of a white or almost white suspension, crystalline precipitate of isophane human insulin 100 IU/ml in an isotonic phosphate buffer. 1 ml of suspension contains 100 IU of insulin human recombinant (100 % crystalline protamine-insulin).
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes. Insulins and analogues for injection, intermediate-acting. ***Code ATC:*** A10A C01.
	Reference to Finished product specifications	Monograph “Insulin injection, isophane”, Ph. Eur
	Proposed Pack size	- 3 ml in cartridge, 5 cartridges in package;
	Proposed unit price	As per SRO & Retrospective CPIs
	Shelf Life	36 Months
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Humulin NPH “Eli Lilly” (USA) 100IU/mL
	For generic drugs (me-too status)	HUMULIN-'N' Injection (Eli Lilly & CO, Ali Gohar & Co, Karachi) Reg. No.: 008299
	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	Name: Private Joint-Stock Company "On the production of insulin "INDAR" Address: 5, Zroshuvalna Str, Kyiv, 02099, Ukraine.

	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 Insulin human recombinant powder substances at accelerated and real time (long term) conditions. The real time (long term) stability data is conducted at -18°C and lowered for 3 years.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted Assay Method Validation by performing linearity, accuracy, precision, and robustness.
	Container closure system of the drug product	**Package in cartridges** 3.0 ml of a medicinal product is filled in vial-cartridge, made from a transparent, colourless glass, hydrolytic type I (Ph. Eur.), tight closured by rubber plunger (Type I). On the other side cartridges are closured with combination seals consisting of rubber liner (Type I) with aluminium crimp cap. Type of vial-cartridge: Vial-cartridge made from transparent, colourless glass, hydrolytic class I (Type I) (Ph. Eur.) with inner siliconization. Type of rubber liner and plunger: Type I (Ph. Eur.)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. **For 3 ml in cartridge** The accelerated stability study data is conducted at 25°C±2°C for 6 months. The long-term stability study data is conducted at 5°C±3°C for 40 months (stable during 36 months). Batch no. 0010214, 0010315, 10116
	Module IV	Summarized in Biosimilarity data
	Module V	Summarized in Biosimilarity data
	The firm has submitted Biosimilarity data as per following details:	

WHO Biosimilarity Guidelines	**Data Submitted by M/s Galaxy Pharma (Pvt.) Ltd. Karachi**
Quality Comparison Physicochemical Characterization	Insulin human recombinant (100% of crystalline protamine insulin) Humodar B 100R (in 3.0 ml cartridges) in diabetes patients has been compared to Humulin NPH "Eli Lilly" (USA) (in 3.0 ml cartridges).

Category	**Quality Attributes**	**Analytical methods**
Structural characterization	Amino acid sequence Analysis	Peptide mapping and full-length sequencing by LC-ESI-MC AND –MS/MS
	Disulfide Linkage Analysis	LC-ESI-MS and – MS/MS
	N- Terminal sequencing	Edman: 10 Amino acids
Physicochemical properties	Molecular weight or size	By Mass spectroscopy: LC-ESI-MS of intact protein
	Related protein	HPLC Alliance systems with UV/VIS detectors, waters

	<table><tr><td></td><td>Protamine content</td><td>SEC (Thermofisher scientific)</td></tr><tr><td></td><td>Zinc content</td><td>AAS (Thermofisher scientific)</td></tr><tr><td></td><td>Lys-insulin content</td><td>HPLC</td></tr><tr><td></td><td>ModLys-insulin content</td><td>IC (Thermofisher scientific)</td></tr><tr><td></td><td>Particle size distribution</td><td>Laser diffraction particle size analyzer mastersizer 2000, Malvern instruments</td></tr><tr><td></td><td>Microscopic characterization of NPH crystals</td><td>Microscopic Nikon eclipse 80i with camera</td></tr></table>
Comparison of degradation profile (under accelerated stability study stressed condition) (temp +40°C±2°C, RH 75%±5%)	Test equipment – Water HPLC Alliance systems with UV/VIS Detectors The tests performed Insulin assay, high molecular weight proteins, related proteins, related proteins- perchlorate as determined by two orthogonal HPLC methods, one Ph. Eur and the other in-house.
Comparison of degradation profile (exposure to stress condition)	Test equipment – Water HPLC Alliance systems with UV/VIS Detectors Experimental conditions include Acid induced degradation (Ph 2.5), Alkaline induced degradation (Ph 11), Agitation induced degradation, Photodegradation, Oxidative degradation.
Comparison of three-dimensional structure & thermodynamic stability	Instrumentation: - FTIR Spectroscopy - CD spectroscopy - UV-Vis spectroscopy - Fluorescence spectroscopy - Dynamic light scattering - Differential calorimetry The extensive studies using above methods show there is no difference in secondary and tertiary structure between drug substances (highly comparable)
Biological Activity	Cell based Bioactivity Assay – In vivo test in rabbits The biological activity of tested Insulin human was determined in comparison with a standard Insulin human sample using the blood sugar-lowering effect in rabbits. Determination of the biological activity of Insulin human was performed in a certified Quality Control Laboratory of the Indar Company. The test was carried out on 18 rabbits (each weighing 2.5-3.5kg), which were previously determined as sensitive to Insulin human. The solution of the Insulin human (batch 0030108 ИРС) and the standard sample were administered to 18 rabbits divided into the investigational and control groups in quantity of 0.5 IU per 1 kg of the body weight. One hour and 2.5 h after each injection, a suitable blood sample was taken from the ear vein of each rabbit, with subsequent determination of blood glucose. The resulting index of the biological activity of the tested Insulin human satisfied the requirements.
Immunochemical properties	A randomized, open-label, clinical study was conducted in diabetes patients to determine the efficiency of Indar's product Humodar B 100R (in 3.0 ml cartridges) compared to Humulin NPH "Eli Lilly" (USA) (30 patients in each group). The treatment duration averaged to 21 days. Incidence of immune response (formation of antibodies against insulin) in the groups of the study drug and comparison drug in %; - Average therapeutic doses of Humodar B 100R were not different from those ones which were used in reference preparation – Humulin NPH. Statistical analysis showed its significant efficiency compared to Humulin NPH. - Humodar B 100R had a good acceptability in patients. During trials (21 days) no patient had adverse reactions.

<table>
<tr><td></td><td>- Humodar B 100R had a good hypoglycaemic effect in diabetes patients type I and type II diabetes of severe and medium severity level.
- It was concluded that the efficiency of Humodar B 100R was comparable to Humulin NPH of Eli Lilly (USA).</td></tr>
<tr><td>Impurities</td><td>
<table>
<tr><th>Stage of production process</th><th>Type of Impurity</th></tr>
<tr><td rowspan="2">Impurities originating from the culture medium</td><td>Metal ions</td></tr>
<tr><td>Antibiotic</td></tr>
<tr><td rowspan="3">Impurities originating from the cell culture</td><td>Host-cell-derived proteins</td></tr>
<tr><td>Bacterial endotoxins</td></tr>
<tr><td>Host cell DNA</td></tr>
<tr><td rowspan="3">Impurities associated with isolation and purification of the product</td><td>Organic solvents</td></tr>
<tr><td>Proteolytic enzymes</td></tr>
<tr><td>Zinc</td></tr>
<tr><td rowspan="3">Product-related Impurities</td><td>A-21 desamidoinsulin</td></tr>
<tr><td>Insulin-related proteins</td></tr>
<tr><td>High molecular weight proteins</td></tr>
<tr><td>Contamination Microbiological purity</td><td>Contamination Microbiological purity</td></tr>
</table>
</td></tr>
<tr><td>Stability Studies</td><td>The firm has submitted stability studies.</td></tr>
<tr><td>Non-clinical Comparison
I. In-vitro Studies
II. In-vivo Studies
a) Biological / Pharmacodynamic activity
b) Non- clinical Studies</td><td><u>Acute toxicity test</u>: White mice of both sexes. 5 groups of experimental animals (10 mice per group) were formed for testing every medication. Insulin medications were injected as solutions subcutaneously and slowly as single-shots in 10 – 100 IU doses per kg of body weight. The observation was done 14 days after the administration of drug products. “HUMODAR B” semisynthetic insulin suspension for injection, 40 IU/ml, manufactured by the “INDAR” PrJSC (Ukraine) (that previously was registered in Ukraine), was used as the reference product.
There is no difference between the values of LD50. It was concluded that the tested formulation of the medication corresponded to the reference product in values of acute toxicity and clinical pattern.
No evidence of toxic effects was found in proposed doses.</td></tr>
</table>

Clinical Studies	• To evaluate efficiency and acceptability of Humodar B 100R (in 3.0 ml cartridges) in diabetes patients compared to Humulin NPH "Eli Lilly" (USA) (in 3.0 ml cartridges). • Open label, comparative, randomized, multicenter clinical study of the efficiency and acceptability of Humodar B 100R (in 3.0 ml cartridges) in diabetes patients compared to Humulin NPH "Eli Lilly" (USA) (in 3.0 ml cartridges) in patients with diabetes mellitus. -30 in study group (with diabetes mellitus with severe and medium degree of disease: type I –16 pts; type II – 14 pts). -30 in control group (with diabetes mellitus with severe and medium degree of disease: type I –14 pts; type II – 16 pts). • Potency assignment of Humodar, and data collection on adverse reaction in comparison with standard insulin by the means of insulin dependent diabetic patients' treatment. • Randomized crossover clinical study of potency assignment of Humodar in comparison to standard insulin among **73 patients**, divided into 2 groups: (patients in study group and patients in control group) • To study the effect of test drug on the state of carbohydrate metabolism at patients with diabetes type 1 and type 2 (52 patients with diabetes mellitus type I and II in a state of decompensation); To study the tolerance, influence and possible adverse reactions of test drug, to define hypoglycemia frequency and intensity. • To evaluate the efficacy and tolerability of insulin Humodar B 100R for diabetics with type 1 and 2 (20 patients). • The study demonstrated safety and efficacy in the treatment of diabetics. Evaluation of efficacy and tolerability of the drugs Humodar B 100R (100 IU/ml, suspension for injection in 10 ml vials, 3 ml cartridges) (20 patients) produced by CJSC "Indar" (Ukraine) for diabetes type 1 and 2.

<u>Decision:</u> Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and submission of notarized LoA.

9.	Name, address of Applicant / Importer	M/s Galaxy Pharma (Pvt.) Ltd. Address: Plot no. 28-C, Lane no. 09, Ittehad commercial Phase VI, DHA, Karachi-75500 Pakistan.
	Details of Drug Sale License of importer	M/s Galaxy Pharma (Pvt.) Ltd. Address: Plot no. 28-C, Lane no. 09, Ittehad commercial Phase VI, DHA, Karachi-75500 Pakistan. License No.: 124 Valid till: 02.09.2023
	Name and address of marketing authorization holder (abroad)	Name: Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR" Address: 5, Zroshuvalna str, Kyiv, Ukraine, 02099
	Name, address of manufacturer(s)	Name: Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR" Address: 5, Zroshuvalna str, Kyiv, Ukraine, 02099
	Name of exporting country	Ukraine
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (CPP/UA/273/19/4) remains valid until unlimited issued by State Service of Ukraine on Medicine and Drugs Control for HUMODAR R 100R, solution for injection 100IU/mL (1 mL of solution which contains: 100IU insulin human recombinant. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every three years.

		DML: Firm has submitted Original Legalized Drug Manufacturing Licence of manufacturer (Series AB License No. 598072) issued by State Service of Ukraine on Medicine and Drugs Control. The certificate is issued on January 17,2014
		GMP: Firm has submitted Original legalized GMP Compliance No. 062/2019/GMP Drug Manufacturing Licence of manufacturer (Series AB License No. 598072) issued by State Service of Ukraine on Medicine and Drugs Control. The certificate is issued on 04.10.2019.
	Details of letter of authorization / sole agency agreement	Firm has submitted a copy of power of attorney from Chairman of board of Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR". According to the letter, the firm Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN "INDAR" authorizes "Galaxy Pharma (Pvt.) Ltd. Domiciled at basement Plot no. 28-C, Lane no. 09, Ittehad commercial Phase VI, DHA, Karachi Islamic Republic of Pakistan legally represented by Director Regulatory affairs -Saif Ur Rehman to execute all necessary legal actions for registration, post registration changes and renewal of regulatory status of the products manufactured by PrJSC <<INDAR>> in the local regulatory authorities and structural subdivisions of the Ministry of Health of the Islamic Republic of Pakistan and to import, sell, distribute all PrJSC <<INDAR>> products in the Islamic Republic of Pakistan. Further, firm has submitted sole agency Agreement between Galaxy Pharma (Pvt.) Limited and Private Joint-Stock Company "ON THE PRODUCTION OF INSULIN" INDAR". issued on December 31, 2019 valid for 03 years from date of issue and automatically renewed for subsequent 3 (three) years.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy. No. 27647; Dated 19-10-2020
	Details of fee submitted	**Pack size** | **Slip no.** | **Date** - 3 ml in cartridge, 5 cartridges in package | (Rs. 100,030/-) Slip No. 1979380 | 02-10-2020
	The proposed proprietary name / brand name	**HUMODAR R 100R, solution for injections, 100 IU/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Insulin human (r-DNA) ……..... 100 IU/ml. Synonym of the applied drug – Insulin soluble
	Pharmaceutical form of applied drug	HUMODAR R 100R, a solution for injections in a cartridge or vial, a sterile, clear, colourless, aqueous solution of human insulin, 100 IU/ml.1 ml of injections solution contains 100 IU of insulin human recombinant. Injection finished product formulation is manufactured with no overage of the active substance.
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes. Insulins and analogues for injection, fast-acting. ***Code ATC:*** A10A B01.

	Reference to Finished product specifications	Monograph “Insulin injection, soluble”, Ph. Eur.
	Proposed Pack size	- 3 ml in cartridge, 5 cartridges in package;
	Proposed unit price	As per SRO & Retrospective CPIs
	Shelf Life	2 years (24 months)
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	«HUMULIN REGULAR, solution for injection, 100 IU/ml, 10 ml in vials» production by company «Eli Lilly» (USA)
	For generic drugs (me-too status)	HUMULIN-'R' Injection (Eli Lilly & CO, Ali Gohar & Co, Karachi) Reg. No.:008302, 008301
	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	Name: Private Joint-Stock Company "On the production of insulin "INDAR" Address: 5, Zroshuvalna Str.,Kyiv, 02099, Ukraine
	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 Insulin human recombinant powder susbtances at accelerated conditions 5°C± 3°C. The long term stability data is conducted at -18°C and lowered for 3 years.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted Assay Method Validation by performing linearity, accuracy, precision, and robustness.
	Container closure system of the drug product	**Package in cartridges** 3.0 ml of a medicinal product is filled in cartridge, made from a transparent, colourless glass of I hydrolytic class (Type I), siliconed inside, tight closured by rubber plunger. On the other side cartridges are closured with combination seals consisting of rubber linear with aluminium crimp cap. Cartridge is labelled with label. 3 or 5 cartridges together with insert leaflet are packed into an individual pack made from a cardboard. Cover of a pack should be closed with the help of lock-clasps. <u>Type of vial-cartridge:</u> Vial-cartridges made from transparent, colourless glass, hydrolytic class I (Type I) (Ph. Eur., current edition) with inner siliconization <u>Type of rubber liner and plunger:</u> Type I (Ph. Eur., current edition) – bromobutyl rubber
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. **For 3 ml in cartridge**

		The accelerated stability study data is conducted at 25°C±2°C for 6 months. The long-term stability study data is conducted at 5°C±3°C for 2 years. Batch no. 0010414, 0010315,10116
	Module IV	Summarized in Biosimilarity data
	Module V	Summarized in Biosimilarity data
	The firm has submitted Biosimilarity data as per following details:	

WHO Biosimilarity Guidelines	**Data Submitted by M/s Galaxy Pharma (Pvt.) Ltd. Karachi**
Quality Comparison Physicochemical Characterization	Insulin human (r-DNA) from INDAR has been compared to Insulin human (r-DNA) Humulin "Eli Lilly" (USA) (Reference drug).

Category	**Quality Attributes**	**Analytical methods**
Structural characterization	Amino acid sequence Analysis	Peptide mapping and full-length sequencing by LC-ESI-MC AND –MS/MS
	Disulfide Linkage Analysis	LC-ESI-MS and – MS/MS
	N- Terminal sequencing	Edman: 10 Amino acids
Physicochemical properties	Molecular weight or size	By Mass spectroscopy: LC-ESI-MS of intact protein
	Related protein	HPLC Alliance systems with UV/VIS detectors, waters
	Protamine content	SEC (Thermofisher scientific)
	Zinc content	AAS (Thermofisher scientific)
	Lys-insulin content	HPLC
	ModLys-insulin content	IC (Thermofisher scientific)
	Particle size distribution	Laser diffraction particle size analyzer mastersizer 2000, Malvern instruments
	Microscopic characterization of NPH crystals	Microscopic Nikon eclipse 80i with camera

Comparison of degradation profile (under accelerated stability study stressed condition) (temp +40°C ± 2°C, RH 75% ± 5%)	Test equipment – Water HPLC Alliance systems with UV/VIS Detectors The tests performed Insulin assay, high molecular weight proteins, related proteins, related proteins- perchlorate as determined by two orthogonal HPLC methods, one Ph. Eur and the other in-house.
Comparison of degradation profile (exposure to stress condition)	Test equipment – Water HPLC Alliance systems with UV/VIS Detectors Experimental conditions include Acid induced degradation (Ph 2.5), Alkaline induced degradation (Ph 11), Agitation induced degradation, Photodegradation, Oxidative degradation.
Comparison of three-dimensional structure & thermodynamic stability	Instrumentation: - FTIR Spectroscopy - CD spectroscopy - UV-Vis spectroscopy

<table>
<tr><td></td><td>- Fluorescence spectroscopy
- Dynamic light scattering
- Differential calorimetry
The extensive studies using above methods show there is no difference in secondary and tertiary structure between drug substances (highly comparable).</td></tr>
<tr><td>Biological Activity</td><td>Cell based Bioactivity Assay – In vivo test in rabbits
Biological activity of HUMODAR® R 100R was tested on 2.5 – 3.5 kg rabbits with the help of comparison of its expected activity with the biological activity of the standard insulin sample. 15 mg (precise batch) of the standard human insulin sample with the activity of 26 IU/mg was dissolved in 10 ml 0.003 M hydrochloric acid. 5 ml of received solution was diluted with phosphate buffer pH 7.4 to 100 ml. Biological activity of the insulin medication was examined no sooner than in 7 days after testing animals' insulin sensitivity. Animals chosen for examination were divided into 2 groups (control and research) (10 animals in each).</td></tr>
<tr><td>Immunochemical properties</td><td>A randomized, open-label, clinical study was conducted in diabetes patients to determine the efficiency of Indar's product Humodar R 100R compared to Humulin Regular "Eli Lilly" (USA) (30 patients in each group). All patients were also co-administered with 2-3 daily injections of short- acting Insulin preparation Humodar R. The treatment duration averaged to 21 days.
- Based on data of clinical trials stipulated in the report sugar lowering efficiencyof HUMODAR R 100R was proved in the course of treatment with HUMODAR R 100Rdiabetes patients what testify probable glycaemia lowering in the course of transfer to the administration of the tested preparation.
- HUMODAR R 100R is rational to use for intensify insulintherapy with high level of postprandial glycaemia and before each meal intake.
- Sugar lowering effect of HUMODAR R 100R was achieved by average daily dose of the preparation, which was not considerable different from the insulin dose of insulin which was used in control group previously.
- Clinical trials of preparation showed good tolerability and safety of HUMODAR R 100R and no ocuurence of adverse reactions.
- It was concluded that the efficiency of Humodar R 100R was comparable to Humulin R of Eli Lilly (USA).</td></tr>
<tr><td>Impurities</td><td>
<table>
<tr><th>Stage of production process</th><th>Type of Impurity</th></tr>
<tr><td rowspan="2">Impurities originating from the culture medium</td><td>Metal ions</td></tr>
<tr><td>Antibiotic</td></tr>
<tr><td rowspan="3">Impurities originating from the cell culture</td><td>Host-cell-derived proteins</td></tr>
<tr><td>Bacterial endotoxins</td></tr>
<tr><td>Host cell DNA</td></tr>
<tr><td rowspan="3">Impurities associated with isolation and purification of the product</td><td>Organic solvents</td></tr>
<tr><td>Proteolytic enzymes</td></tr>
<tr><td>Zinc</td></tr>
<tr><td rowspan="3">Product-related Impurities</td><td>A-21 desamidoinsulin</td></tr>
<tr><td>Insulin-related proteins</td></tr>
<tr><td>High molecular weight proteins</td></tr>
<tr><td>Contamination Microbiological purity</td><td>Contamination Microbiological purity</td></tr>
</table>
</td></tr>
<tr><td>Stability Studies</td><td>The firm has submitted stability studies.</td></tr>
<tr><td>Non-clinical Comparison
III. In-vitro Studies
IV. In-vivo Studies
c) Biological / Pharmacodynamic activity
d) Non- clinical Studies</td><td><u>Acute toxicity</u>: tested for HUMODAR R 100R pharmaceutical drug based on recombinant human insulin substance and compare to the reference product (HUMODAR R solution for injection 40 IU/ml, in 10 ml vial, semi-synthetic human insulin solution (fast –acting insulin)).
white mice of both sexes. 100 mice (50study group, 50 control group)
<u>Biological activity:</u> HUMODAR® R 100R was tested on 2,5 – 3,5 kg rabbits with the help of comparison of its expected activity with the biological activity of the standard insulin solution sample. Repeated experiment for estimation of rabbits' blood glucose concentration was conducted in 3. 40 rabbits (20 study group, 20 control group).</td></tr>
</table>

Clinical Studies	• To evaluate efficiency and acceptability of Humodar R 100R (in 3.0 ml cartridges) in diabetes patients compared to Humulin NPH "Eli Lilly" (USA) (in 3.0 ml cartridges). • Open label, comparative clinical study of the efficiency and acceptability of Humodar R 100R (in 3.0 ml cartridges) in diabetes patients compared to Humulin NPH "Eli Lilly" (USA) (in 3.0 ml cartridges) in patients with diabetes mellitus. • 30 in study group (with diabetes mellitus with severe and medium degree of disease: type I –19 pts; type II – 11 pts). • 30 in control group (with diabetes mellitus with severe and medium degree of disease: type I –17 pts; type II – 13 pts). Controlled clinical studies pertinent to the claimed indication. • Randomize crossover study, **73 diabetic patients** who are taking a course of treatment with premixed insulin or fast and slow acting insulin (prolonged and rapid-acting insulin) underwent testing on a voluntary basis. • Potency assignment of Humodar, and data collection on adverse reaction in comparison with standard insulin by the means of insulin dependent diabetic patients' treatment. • Randomized crossover clinical study of potency assignment of Humodar in comparison to standard insulin among **73 patients**, divided into 2 groups: (patients in study group and patients in control group). • To study the effect of test drug on the state of carbohydrate metabolism at patients with diabetes type 1 and type 2 • To study the tolerance, influence and possible adverse reactions of test drug, to define hypoglycemia frequency and intensity. • To study the influence of test drug on the quality of patient's lives. • Open Non-comparative study on the one group of patients (**52 patients** with diabetes mellitus type I and II in a state of decompensation); • To evaluate the efficacy and tolerability of insulin Humodar R 100R for diabetics with type 1 and 2. • A third phase of the open non-comparative, multicenter study of efficacy and safety of insulin Humodar R 100R based on one group of diabetes. (20 patients) • Evaluation of efficacy and tolerability of the drugs Humodar R 100R (100 IU/ml, solution for injection in 10 ml vials, 3 ml cartridges) (**20 patients**) produced by CJSC "Indar" (Ukraine) for diabetes type 1 and 2.
<u>Decision:</u> Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Imported Veterinary Biologicals from Non-Reference Countries:

10.	Name of Importer	M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha.
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20 –November 2023.
	Marketing authorization holder	M/s Komipharm International Co. Ltd. 17,Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of Manufacturer	M/s Komipharm International Co. Ltd. 17, Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of exporting country	South Korea
	Brand Name +Dosage Form + Strength	PRO-VAC AB
	Diary No. Date of R& I & fee	Dy no. 20099 (R&I); Dated 14-07-2022 Rs.100,000 (Slip No.0735196)
	Composition	Composition of dose (2mL/1 dose): Anthrax (Stern Strain) culture solution suspended in 50% glycerin……...47.5% Anthrax (Stern Strain) spore ……..…≥ 0.8×10^7 CFU Attenuate Black Leg Culture solution……47.5% Black leg spore……≥ 2.0×10^6 CFU
	Pharmacological Group	Attenuated bacterial veterinary vaccine

	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-5°C)
	Pack size and demanded price	20 ml vial / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	N/A
	Stability data of finished product	The firm has submitted stability study data of 27 months observation period conducted at 2°C to 5°C for three batches as below: 56 AB 01 56 AB 02 56 AB 03
	Document Details	• Legalized GMP Certificate (No. M2203483) issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea on 15-03-2022. • Legalized FSC (No. M2011076) issued on 31-08-2020 by Animal and plant quarantine agency, Ministry of Agriculture, Food and Rural affairs of Republic of Korea, confirms that product is on free sale in the market of Republic of Korea. • Copy of product specific sole agency agreement.
	Remarks of Evaluator: Evidence of already registered product in applied strains could not be verified.	
	<u>Decision:</u> Dr. Qurban Ali, Co-opted member Registration Board deliberated that Anthrax Stern strain is currently the predominant strain used for immunization of domesticated animals against anthrax worldwide. The strain is a virulent for vaccine production and is able to stimulate a protective immune response. **The Board after thorough deliberation decided to refer the case to Expert Working Group for review of formulation as the formulation contains Anthrax Spore.**	
11.	Name of Importer	M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th –November 2023
	Marketing authorization holder	M/s Komipharm International Co. Ltd. 17,Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of Manufacturer	M/s Komipharm International Co. Ltd. 17, Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of exporting country	South Korea
	Brand Name +Dosage Form + Strength	PRO-VAC H5-AINK Inactivated poultry vaccine
	Diary No. Date of R& I & fee	Dy no. 20105 (R&I); Dated 14-07-2022 Rs.75,000 (Slip No.64205171)
	Composition	Each 0.5mL contains: HA Recombinant antigen of H5 type highly pathogenic Avian Influenza virus [(H5N1), (H5N6) derived HA protein] ….……≥ $2^{9.0}$ HA Unit Newcastle Disease virus (Ulster 2C strain), before inactivation……≥ $10^{8.5}$ EID_{50}
	Pharmacological Group	Inactivated veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	500 ml PP bottles / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	Gallimune Flu H5N9 injectable vaccine of Saadat International (Reg#043501)
	Stability data of finished product	The firm has submitted stability study data of 24 months' observation period conducted at 2°C to 8°C for three batches as below: KM-H5ANK-01

		KM-H5ANK-02 KM-H5ANK-03
	Document Details	• Legalized GMP Certificate (No. M2203483) issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea on 15-03-2022. • Legalized FSC (No. M2203493) issued on 15-03-2022 by Animal and plant quarantine agency, Ministry of Agriculture, Food and Rural affairs of Republic of Korea, confirms that product is on free sale in the market of Republic of Korea. • Copy of product specific sole agency agreement.
	Remarks of Evaluator: The locally available strain is H5N9 while applied vaccine strains are H5N1 and H5N6.	
	<u>Decision:</u> Registration Board after discussion on the matter decided to defer the case for further deliberations.	
12.	Name of Importer	M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha
	DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th –November, 2023
	Marketing authorization holder	M/s Komipharm International Co. Ltd. 17,Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of Manufacturer	M/s Komipharm International Co. Ltd. 17, Gyeongje-ro, Siheung-Si, Gyeonggi-do, South Korea
	Name of exporting country	South Korea
	Brand Name +Dosage Form + Strength	PRO-VAC FT-Oil Inactivated poultry vaccine
	Diary No. Date of R& I & fee	Dy no. 20104 (R&I); Dated 14-07-2022 Rs.75,000 (Slip No.411547807965)
	Composition	Each 0.5mL contains: Inactivated Salmonella enterica serovar gallinarum culture (6.3×10^{10} / mL ~ 6.9×10^{10} / mL)……39.7%
	Pharmacological Group	Inactivated veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months (2°C-8°C)
	Pack size and demanded price	500 ml PP bottles / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	Avisan Secure of M/s Hipra laboratories, Spain
	Stability data of finished product	The firm has submitted stability study data of 24 months' observation period conducted at 2°C to 8°C for three batches as below: 54FTOV06 54FTOV07 54FTOV08
	Document Details	• Legalized GMP Certificate (No. M2203483) issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea on 15-03-2022. • Legalized FSC (No. M2203490) issued on 15-03-2022 by Animal and plant quarantine agency, Ministry of Agriculture, Food and Rural affairs of Republic of Korea, confirms that product is on free sale in the market of Republic of Korea. • Copy of product specific sole agency agreement.
	Remarks of Evaluator:	
	<u>Decision:</u> Registration Board after discussion on the matter decided to defer the case for further deliberations.	

Imported Veterinary Biologicals from Reference Countries:

Cancellation of Registration of Avipro Salmonella DUO of M/s Eli Lilly Pakistan (Pvt) Limited Karachi and grant of same brand to M/s Golden Harvest, Karachi on the NOC of M/s Eli Lilly Pakistan (Pvt) Limited Karachi

M/s Golden harvest, Karachi applied for registration of following veterinary biologicals in their name from M/s Eli Lilly Pakistan (Pvt.) Ltd., Karachi:

13.	**Name of Importer**	**M/s Golden Harvest,** Address: Plot No. 49-C, 24th Commercial Street Phase-II Extt: DHA, Karachi.
	DSL details	License to sell drug as distributor No. 054 valid till 26-02-2023
	Marketing authorization holder	**Lohmann Animal Health** Heinz-Lohmann-StraBe 4, 27472 Cuxhaven, Germany.
	Name of Manufacturer	**Lohmann Animal Health** Heinz-Lohmann-StraBe 4, 27472 Cuxhaven, Germany
	Name of exporting country	Germany.
	Brand Name +Dosage Form + Strength	Avipro Salmonella DUO
	Diary No. Date of R& I & fee	Dy. No. 2542 (R&I); Dated 21-01-2021 Rs.100,000 (Slip No.0711592)
	Composition	Composition per dose: 1 dose contains Each dose contains: Live Salmonella Enteritidis bacteria, strain Sm24/Rif12/Ssq, Atleast 1 x 10^8.0 CFU* Live Salmonella Typhimurium bacteria, strain Nal2/Rif9/Rtt, Atleast 1 x 10^8.0 CFU* *CFU = Colony Forming Units
	Pharmacological Group	Live Freeze dried bacterial veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. Specification
	Shelf Life	18 months (2°C-8°C)
	Pack size and demanded price	10 × 2000 dose vial / Decontrolled
	International availability	Germany, EU , UK,
	Products already registered in Pakistan	Avipro Salmonella DUO is already registered in Pakistan as an innovative product with Reg no**. 083177**.
	Stability data of finished product	The firm has submitted stability study data of 26 months conducted at 2°C to 8°C for three consecutive batches as below: 200308-1C 200312-2C 200401-3C
	Document Details	• Legalized Free Sale Certificate No. 048/LAH/2020.issued by State Office for Consumer Protection and Food Safety, Germany (Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit) Dated: 10/08/2020 • Legalized GMP Certificate No.075/LAH/2018 Dated: 23 Feb 2018.

Remarks of Evaluator
Valid copy of Drug sale license is required to be submitted.

Sr. No.	**Decision of 317th meeting of RB**	**Response by the firm**
1.	Original termination letter from manufacturer abroad for previous importer.	Original Letter of Termination dated 11/03/22 submitted by Firm
2.	Valid legalized approval of 21 months shelf life issued by regulatory authority of country of origin.	The firm has submitted revised Form 5A with correct shelf life for 18 months' shelf life which can be verified from online database of Germany.

3.	Real time stability data for both products including all the parameters as mentioned in finished product specifications. Only test for bacterial counts and residual moisture (%) have been provided. While as per CoA four tests are performed, i.e. identification of active substance, viable testing, purity test and residual moisture.	The firm has submitted an Explanation Letter regarding the vaccine AviPro Salmonella DUO: According to our previous explanation in the stability justification letter on March 12, 2022, the provisions that are taken in the account regarding veterinary vaccines in the European Union (EU), Germany, are the ones defined in monograph no. 62 of the European Pharmacopoeia (EP), section 2-2-3-Stability. *"For a live freeze-dried bacterial veterinary vaccine like the one we are dealing with, the bacterial counts and residual moisture testing are the parameters to be studied, and both have been tested in the provided stability trial.* *Monitoring all the parameters defined in batch release (CoA) is not a common practice as per se it has not added value. Only monitoring the parameters that may change and therefore influence on the quality and shelf-life of a veterinary vaccine are the ones to be controlled."* Having said that, regarding the 4 parameters mentioned by the Board: identification of active substance viable testing purity test residual moisture Viable testing (which are the bacterial count test) and residual parameters were assayed in the stability trial. In relation to the identification of the active substance, this a bivalent live bacterial vaccine composed by *Salmonella* Enteritidis and *Salmonella* Tiphymurium. *The full identification profile was done at batch release.* The characteristics to identify these 2 *Salmonella* serotypes do not change over time. Chemically-defined substances may change over time, but, for bacteria, if grown during shelf-life (confirmed by the viable bacterial count), they do not change its identity and therefore it does not need to be reconfirmed. In relation to purity, this test was also carried out at batch release. Once purity is confirmed, the vaccine is already manufactured, so filled in, freeze-dried and sealed. The vial is no longer manipulated and therefore it cannot be (re-contaminated). This is why purity is another parameter that does not need to be reconfirmed. To summarize, we would like to highlight that the 4 parameters the 2 critical ones (already mentioned in the EP) were carried out in the trial, and the 2 other ones were duly checked at batch release, are not susceptible to change over time and cannot influence shelf-life."

<u>Decision:</u> Registration Board decided to provide the opportunity of personal hearing to M/s Eli Lilly Pakistan (Pvt) Limited Karachi under section 42 of the Drugs Act, 1976 of schedule VI of DRAP Act 2012 for cancellation of Registration of Avipro Salmonella DUO of M/s Eli Lilly Pakistan (Pvt) Limited Karachi and as per NOC of M/s Eli Lilly Pakistan (Pvt) Limited Karachi,

	the case shall also be considered for grant of registration of said product to M/s Golden Harvest, Karachi after personal hearing.

CASES OF DD-III (Ms. HALEEMA SHARIF)

Imported Human Biologicals from Non-Reference Countries

M/s Bio Link (Pvt) Ltd., Karachi applied for the registration of following human biologicals:

Sr. No.	Name of Manufacture	Name of Product	Dy. No., Date of Application & Fee Status/ Pack Size
14.	M/s Sichuan Yuanda-Shuyang Pharmaceutical Co., Ltd., China	SUYA-HB 100 IU/mL	Dy. No.9721(R&I) Dated 11-02-2021 Rs.100,000/- 1's vial
15.		SUYA-HR 200 IU/mL	Dy.No.9722 (R&I) Dated 11-02-2021 Rs.100,000/- Dated 11-02-2021 1's vial

It is pertinent to mention that firm has submitted applications on Form-5A instead of Form-5F (CTD). Applicant was advised vide this division letter dated 10th February, 2022 to submit following documents for further processing of the case:

a. Applications on Form-5F (CTD) for both products.
b. Original valid legalized CoPP/ FSC & GMP.
c. Original or Notarized copy of letter of sole agency authorization.

Now the firm M/s Bio Link (Pvt) Ltd., Karachi in their reply on 27th January 2023 submitted following:

a. Module I of Form-5F (CTD) for both products which is also incomplete.
b. Original valid legalized CoPP for SUYA-HB 100 IU/mL & SUYA-HR 200 IU/mL
c. Copy of letter of sole agency authorization for product SUYA-HB 100 IU/mL only.

Evaluation by DBER:
It is submitted that both application of firm is still incomplete for following documents:

i. Module I (In-complete)
ii. Module II
iii. Module III
iv. Module IV
v. Module V
vi. Original or notarized copy of sole agency authorization for both products

Decision: Registration Board deferred the case for the following:

i. Submit Applications on Form-5F (CTD)including all its modules for both products.
ii. Original or notarized copy of sole agency authorization for both products.

Imported Veterinary Biologicals from Reference Countries

16.	**Name and address of Importer**	**M/s UM Enterprises,** **Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900**
	Detail of DSL	**M/s UM Enterprises** Address: Plot No. 12 Sector 15 K.I.A Karachi. Valid till: 22-03-2021 to 21-03-2023
	Name and address of Manufacturer	**Manufacturer of Drug:** Zoetis Inc 2000 Rockford Road Charles City, IA 50616-9989 USA

	Name of exporting country	USA
	Brand Name +Dosage Form + Strength	**PoulVac Procerta HVT-IBD**
	Diary No. Date of R& I & fee	Dy. No. 4061 R&I Dated 11-02-2022 Rs. 150,000/- (Slip No. 51970990312)
	Composition	Each 0.2 ml dose contains: HVT ≥ 3,336 PFU/dose at release IBDV ≥ 3,302 PFU/dose at release
	Pharmacological Group	Anti – Infective
	Type of Form	Form-5A
	Finished Product Specification	As per Innovator's specifications
	Shelf Life	24 months (In the vapor or liquid phase of liquid nitrogen)
	Document Details	Certificate of licensing and inspection (Certificate No. 21-01074) is submitted by the firm. **Sole Agency Agreement:** **Zoetis Inc** a corporation existing under the laws of USA, hereby authorizes; M/s UM Enterprises our sole agent in Pakistan for Bursal disease- Marek Disease Vaccine, Serotype 3 Live marek disease vector, USDA product code 1A88.R3
	Pack size	4000 doses
	Reference Regulatory Authority Availability	Approved by USDA
	Products already registered in Pakistan	Could not be confirmed with this combination

Remarks of Evaluator:

It is submitted that Expert opinion of Dr Qurban Ali Member Registration Board is received for PoulVac Procerta HVT-IBD 2000 doses which could also be considered in deciding this case as composition is same only No. of doses are different.

Expert opinion of Dr Qurban is as under:

Opinion of Dr Qurban Ali, Member Registration Board.

Kindly refer to your letter (i) F.No.1-15/2018-AD (BD) Vol. I dated Islamabad the 1st June, 2022 on the subject noted above. Please find below the opinion on the products namely as follows:

Poulvac Procerta HVT-IBD (Marek's Disease + Bursal Disease Vaccine) applied by M/s UM Enterprise, Karachi

Marek's disease (MD), and Infectious bursal disease (IBD) prevail is Pakistan and vaccination against these diseases are routine and therefore need remain. MD vaccine is not produced in the country and the IBD vaccine having varying quality produced locally are not normally used by commercial expensive parent and breeder flocks and at hatcheries producing layers and broilers chicks.

MD and IBD viruses are contagious pathogens that lead to poor field performance and condemnations. MD and IBD lead to immunosuppression, which predisposes both young and older birds to secondary infections. Moreover, the vaccine can especially help raising flocks without antibiotics, through establishing early, robust immunity through vaccination; similarly, it had advantage of control of two diseases with one dose.

The product is of USA origin by M/s Zoetis Inc. USA. M/s Zoetis has over 65 years' experience of animal health and over 20 years in-ovo expertise. The applied vaccine is a frozen, cell associated, live virus vaccine that contains the Marek's disease recombinant serotype 3 turkey herpesvirus (which is widely known to be safe and protect against Marek's disease) with the VP2 gene from infectious bursal disease virus. The product has been shown to be effective for the vaccination of healthy one-day-old chickens and 18- to 19-day-old embryonated chicken eggs against IBD and MD. The duration of immunity against standard IBD is at least 63 days; efficacy and safety data is also available at *productdata.aphis.usda.gov*. The vaccine is packaged in glass ampoules and supplied with diluent packaged in a separate container. The vaccine ampoules are inserted in metal canes, stored and shipped in a liquid nitrogen container. The product is used either s/c injection or in-ovo-injection.

	Based on continued need and advantages of quality, efficacy and safety, the product is recommended for registration with explicit warning on label *[Do not vaccinate within 21 days before slaughter. Use entire contents when first opened. Inactivate unused contents before disposal of empty vials]*.
	Decision: Keeping in view valid legalized Certificate of licensing and inspection indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Imported Veterinary Biologicals from Non-Reference Countries

17.	**Name and address of Importer**	**M/s. Jovac Global-PAK,** Plot No. 17, Block D, EME, DHA Phase 12, Lahore
	Detail of DSL	M/s. Jovac Global-PAK Address: 4th floor, Plot No.17, Block D, EME DHA, Phase 12 Lahore. Valid up to:15.06.2023
	Name and address of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
	Name of exporting country	Jordan
	Brand Name +Dosage Form + Strength	Jova Zeit 6 Plus vaccine. (Injectable oil emulsion)
	Diary No. Date of R& I & fee	Dy. No. 25502 R&I Dated 14-09-2022 Rs. 150,000/- (Slip No. 9269169953)
	Composition	Each dose contains: Inactivated Adenovirus Serotype 2,4 &8 at least…. $10^{6.5}$ $TCID_{50}$
	Pharmacological Group	Inactivated Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	2 years (2^0C-8^0C)
	Document Details	a. Valid legalized free sale certificate is submitted by the firm however it does not confirm the availability of product in country of origin. b. Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020.
	Pack size	300ml(1000doses)
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	GPVAC Hydro TC Plus of Grand Pharma Each 0.3ml contains: Inactivated Avian Adenovirus 4…. $\geq 7\log_{10}$ EID_{50}/dose Inactivated Avian Adenovirus-8…. $\geq 7\log_{10}$ EID_{50}/dose
	Remarks of Evaluator	i. Free sale certificate does not confirm the free sale status of product in country of origin. ii. Locally registered product contains Adenovirus serotype 4 & 8 but not serotype 2.
	Decision: Registration Board deferred the case for the following: • **For submission of valid legalized Free Sale Certificate indicating product availability in country of origin.** • **For submission of evidence of locally registered product containing all serotypes.**	

Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd. Islamabad deferred in 323rd meeting of Registration Board.

18.	**Name and address of Importer**	**M/s Vety Care (Pvt.) Ltd.** **Plot No. 77, Street No.6, I-10/3 Islamabad.**
	Detail of DSL	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
	Name and address of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands
	Brand Name +Dosage Form + Strength	**Innovax ND-IBD**
	Composition	Each dose(ml) contains: Live Herpesvirus of turkey strain HPV 360*….at least $10^{3.3}$PFU** * HPV 360 is a HVT-based recombinant encoding the NDV F protein and the IBDV VP2
	Finished Product Specification	Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf Life	36 months (Liquid Nitrogen)
	International availability	Not Provided.
	Products already registered in Pakistan	Not Available as per record.
	Type of Form Dy. No. & Date of application, Fee submitted	Form-5A Dy. No. 11337(R&I) Dated 28-03-2018 Rs. 100000/- 28-03-2018
	Demanded Price / Pack Size	1's Vial (2000 doses)
	General documentation	Valid legalized CoPP No. 249030 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands.
	Remarks of Evaluator	The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration. Real time stability data provided is of 0, 6, 12, 18, 24, 30, 36, 39 months instead of appropriate time intervals and only titer is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.
	Decision of RB in 288th meeting:	"Registration Board deferred the case for submission of following by the firm: a. Approval status of above product registration by reference regulatory authorities. b. Complete stability data indicating all the parameters tested in COA."
	Evaluation by DBER	The firm has now submitted the following: a. Copy of market authorization approval of product issued by Icelandic Medicine Agency.

		b. As per Intervet the stability data already provided as per European Union Guidelines, and is being accepted all over the world.
	Decision of RB in 292nd meeting:	Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.
	Evaluation by expert working group on veterinary drugs	Referred the case for expert opinion from Ministry of National Food Security & Research, Islamabad.
	Decision of RB in 313th meeting	Deferred for expert opinion from Ministry of National Food Security & Research, Islamabad.
	Evaluation by DBER	Expert opinion from Ministry of National Food Security & Research, Islamabad placed in 317th RB meeting: This is vector vaccine for gumboro(IBD) already 2 similar vaccines are available in Pakistan. May be recommended for import for making healthy competition.
	Decision of RB in 317th meeting	*As the firm had not submitted valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies till 317th RB meeting so the Registration Board in its 317thmeeting decided as under:* ***Deferred the product for submission of valid legalized CoPPs indicating products availability in country of origin and European Union Guidelines regarding stability studies.***
	Evaluation by DBER	***Now the firm has submitted following:*** *Original legalized COPP indicating product availability in country of origin (firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP).* *European Union Guidelines regarding stability studies of veterinary vaccine wherein time interval for stability studies is 0,3,6, 9… months but stability studies of applied formulation* are at *0, 6, 12, 18, 24, 30, 36, 39 months' time intervals*
	Decision of 323rd RB meeting	Deferred for the following: • For Submission of complete stability data indicating all the parameters tested in COA and on all time points as recommended by European Union Guidelines. • For clarification regarding status of product would it be in combo pack or otherwise as firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP.
	Evaluation by DBE&R	Now the firm has submitted following: Stability studies data of three batches (1000 doses,2000doses,4000doses ampoule) for 36 months at storage in liquid nitrogen at 0,3,6….36 time intervals at following parameters; • Identity • Virus titer • Sterility • Mycoplasma • Extraneous Agents We Intervet International B.V., Boxmeer, The Netherlands, hereby declare that product Innovax-ND-IBD is not a combo pack, hence applied for registration separately. The diluent (Nobilis Diluent CA) is already registered in Pakistan with registration number 081293.
	<u>Decision:</u> Keeping in view valid legalized free sale certificate indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Imported Veterinary Biological applied by M/s UM Enterprises. Islamabad deferred in 316th meeting of Registration Board.

19.	**Name and address of Importer**	**M/s UM Enterprises,** **Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900**
	Detail of DSL	**M/s UM Enterprises** Address: Plot No. 12, Sector 15, Korangi Industrial Area. Karachi Valid till: 21-03-2023
	Name and address of Manufacturer	**Manufacturer of Drug:** Zoetis Inc 2000 Rockford Road, Charles City, IA 50616-9989, USA
	Name of exporting country	USA
	Brand Name +Dosage Form + Strength	**PoulVac Procerta HVT-IBD**
	Diary No. Date of R& I & fee	Dy. No. 19420 R&I Dated 12-07-2021 Rs. 150,000/- (Slip No. 35462077)
	Composition	Each 0.2 ml dose contains: HVT ≥ 3,336 PFU/dose at release IBV ≥ 3,302 PFU/dose at release
	Pharmacological Group	Anti – Infective
	Type of Form	Form-5A
	Finished Product Specification	Innovator Specifications
	Shelf Life	24 months (In the vapor or liquid phase of liquid nitrogen) Stability study for 24months is submitted.
	Document Details	**GMP certificate (Original Legalized):** Certificate No. 21-01074 Issued by: U.S. Department of Agriculture Signed On: Feb 18, 2021 **Sole Agency Agreement:** **Zoetis Inc** a corporation existing under the laws of USA, hereby authorizes; M/s UM Enterprises our sole agent in Pakistan for Bursal disease- Marek Disease Vaccine, Serotype 3 Live marek disease vector, USDA product code 1A88.R3 **FSC (Original Legalized):** Certificate No. 21-01074 Issued by: U.S. Department of Agriculture Signed On: Feb 18, 2021
	Pack size	2000 Doses
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Could not be confirmed with this combination
	Decision in 316th RB meeting	Registration Board deferred the case for expert opinion of Dr. Qurban Ali, Member Registration Board regarding immunological relevance of applied combination to Pakistan.

Evaluation by DBE&R:

Subject case of M/s UM Enterprises, Karachi was deferred for expert opinion of Dr. Qurban Ali, Member Registration Board regarding immunological relevance of applied combination to Pakistan, it is submitted that expert opinion of Dr. Qurban Ali has been received via email which is recorded below. Now the firm has applied for correction of typographic error in the composition of subject product and submitted revised Form 5A & fee challan of Rupee 7500/-. Firm has submitted revised composition as under:

Previous Composition	**Revised composition**
Each 0.2 ml dose contains: HVT ≥ 3,336 PFU/dose at release IBV ≥ 3,302 PFU/dose at release	Each 0.2 ml dose contains: HVT ≥ 3,336 PFU/dose at release IBDV ≥ 3,302 PFU/dose at release

Opinion of Dr Qurban Ali, Member Registration Board.

	Kindly refer to your letter (i) F.No.1-15/2018-AD (BD) Vol. I dated Islamabad the 1st June, 2022 on the subject noted above. Please find below the opinion on the products namely as follows: Poulvac Procerta HVT-IBD (Marek's Disease + Bursal Disease Vaccine) applied by M/s UM Enterprise, Karachi Marek's disease (MD), and Infectious bursal disease (IBD) prevail is Pakistan and vaccination against these diseases are routine and therefore need remain. MD vaccine is not produced in the country and the IBD vaccine having varying quality produced locally are not normally used by commercial expensive parent and breeder flocks and at hatcheries producing layers and broilers chicks. MD and IBD viruses are contagious pathogens that lead to poor field performance and condemnations. MD and IBD lead to immunosuppression, which predisposes both young and older birds to secondary infections. Moreover, the vaccine can especially help raising flocks without antibiotics, through establishing early, robust immunity through vaccination; similarly, it had advantage of control of two diseases with one dose. The product is of USA origin by M/s Zoetis Inc. USA. M/s Zoetis has over 65 years' experience of animal health and over 20 years in-ovo expertise. The applied vaccine is a frozen, cell associated, live virus vaccine that contains the Marek's disease recombinant serotype 3 turkey herpesvirus (which is widely known to be safe and protect against Marek's disease) with the VP2 gene from infectious bursal disease virus. The product has been shown to be effective for the vaccination of healthy one-day-old chickens and 18- to 19-day-old embryonated chicken eggs against IBD and MD. The duration of immunity against standard IBD is at least 63 days; efficacy and safety data is also available at *productdata.aphis.usda.gov*. The vaccine is packaged in glass ampoules and supplied with diluent packaged in a separate container. The vaccine ampoules are inserted in metal canes, stored and shipped in a liquid nitrogen container. The product is used either s/c injection or in-ovo-injection. Based on continued need and advantages of quality, efficacy and safety, the product is recommended for registration with explicit warning on label *[Do not vaccinate within 21 days before slaughter. Use entire contents when first opened. Inactivate unused contents before disposal of empty vials]*.
	<u>Decision:</u> Keeping in view valid legalized Certificate of licensing and inspection indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of requisite fee in BE&R division as fee is paid in PE&R division with following compositions after correction of typographic error: **Each 0.2 ml dose contains:** **HVT ≥ 3,336 PFU/dose at release** **IBDV ≥ 3,302 PFU/dose at release**

Imported Veterinary Biological applied by M/s Pharmakon International Enterprises Shamsabad deferred in 324th meeting of Registration Board.

20.	**Name and address of Importer**	**M/s Pharmakon International Enterprises,** Office No. 26, 2nd Floor, Aries Plaza, Murree Road, Shamsabad.
	Detail of DSL	**M/s Pharmakon International Enterprises,** Address: Valid till:
	Name and address of Manufacturer	**Manufacturer of Drug:** M/s JinyuBaoling Bio-Pharmaceutical Co., Ltd. No. 1 Jinyu street, Shaerqin Industrial park, Economic and tecnological Development zone, Hohhot, inner Mongolia, China.
	Name of exporting country	Peoples Republic of China.
	Brand Name +Dosage Form + Strength	Goat Pox Vaccine, Live
	Diary No. Date of R& I & fee	Dy. No. 25395 R&I Dated 13-09-2021 Rs. 150,000/- (Slip No. 33810920261)
	Composition	Each inoculation dose of vaccine contains: Attenuated Goat Pox Virus (Strain CVCC AV41) … $10^{3.5}$ $TCID_{50}$
	Pharmacological Group	Biological

	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's Specifications
	Shelf Life	24months----(-15°C)
	Document Details	**Free Sale Certificate (Original Legalized):** Manufacturer: M/s Jinyu Baoling Bio-Pharmaceutical Co., Ltd Issued by: Department Of Agriculture and Animal Husbandry Of Inner Mongolia Autonomous Region, P.R.China Issue date: 09/03/2020 **GMP Certificate (Original Legalized):** Issued to: M/s JinyuBaoling Bio-Pharmaceutical Co., Ltd. Issued by: Administrative unit: Department Of Agriculture And Animal Husbandry Of Inner Mongolia Autonomous Region, P.R.China Validity: 05-03-2021-04-03-2026 **Sole Agency Agreement:** Product specific Sole agency agreement dated 15th June, 2021 is submitted by the firm
	Pack size & Price	25doses per Vial: Decontrolled
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Could not be confirmed (no any registered product)
	Remarks of Evaluator	Currently there is no any registered Goat pox vaccine. Firm has submitted application for renewal of DSL.
	Decision in 320th Registration Board meeting	Registration Board referred the case to Animal Husbandry Commissioner for comments regarding immunological relevance and need of applied strain in Pakistan.
	Evaluation of DBE&R Division	• *Assistant Animal Husbandry Commissioner vide their letter dated 11th January 2023 submitted following response:* *I am directed to refer to the Drug Regulatory Authority of Pakistan (DRAP) letter No. F.l-15/2018-AD(BD) Vol-I dated 22nd December, 2022 regarding the subject noted above and to say that this Ministry recommends import of Goat Pox Vaccine (Strain CVCC AV41 $10^{3.5}$ $TCID_{50}$) by M/s Pharmakon International Enterprises from china to cater the national needs subject to fulfillment of all codal formalities.* • *Firm has also applied for change in DSL address from office No.23 and 26, second floor, Aries Tower, Shamsabad Murree road, Rawalpindi, Previous DSL No.01-374-0177-0486990 to the new address at:* *First floor Hum Height service road, East near Sohan Interchange, Islamabad and submitted a Fee challan of rupees 7500/-*
	Decision in 324th Registration Board meeting	Registration Board deferred the case for further deliberation regarding need of applied vaccine strain in Pakistan as there is no any registered Goat pox vaccine locally available.
	Decision: Keeping in view valid legalized free sale certificate indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

S. No.	Case title
	PERSONAL HEARING
01	MANUFACTURE & SALE OF SUB-STANDARD MELOVETZ INJECTION, REG. NO. 102021, BATCH NO. 2199017 MANUFACTURED BY M/S. VETZ PHAARMACEUTICALS (PVT.) LTD., KOTRI
02	MANUFACTURE & SALE OF SUB-STANDARD BIOFEN SUSPENSION, REG. NO. 046094, BATCH NO. SP-167, MANUFACTURED BY M/S. BIO-LABS PRIVATE LIMITED, ISLAMABAD.
03	MANUFACTURE & SALE OF SUB-STANDARD TEMPRAMINE SUSPENSION, REG. NO. 011432, BATCH NO. 5TE049, 5TR131, 5TR052 AND 5TR057 MANUFACTURED BY M/S. W. WOODWARD PAKISTAN (PVT.) LTD., KARACHI.
04	MANUFACTURE & SALE OF SUB-STANDARD PANTOLOON TABLET, REG. NO. 095091, BATCH NO. 5602 MANUFACTURED BY M/S. ROCK PHARMACEUTICAL LABORATORIES (PVT) LTD., RISALPUR.
05	MANUFACTURE & SALE OF SUB-STANDARD PROTONIX 40MG TABLETS, BATCH NO. 052 & 069 BY M/S WILSHIRE LABORATORIES (PVT.) LTD., LAHORE.
06	MANUFACTURE & SALE OF SUBSTANDARD KLEVRA ORAL SOLUTION, BATCH NO. 0N152, MANUFACTURED BY M/S. PHARMEVO (PVT.) LTD. KARACHI.
07	SUBSTANDARD 25% DEXTROSE INFUSION B. NO. A042C21 MANUFACTURED BY M/S. OTSUKA PAKISTAN LTD., HUB, BALOCHISTAN
08	MISBRANDED BALINGO INJECTION B. NO. BL-1417 MANUFACTURED BY M/S. BAJWA PHARMACEUTICALS (PVT.) LTD., 36-KM OFF G.T ROAD LAHORE – QCB ISLAMABAD CASE
	APPELLATE TESTING
09	MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION BATCH NO. W-20017 & W-20024, MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.
	ROUTINE CASES
10	MANUFACTURE & SALE OF SUBSTANDARD PARAPALS INFUSION, BATCH NO. LI-100, LI-101 & LI-102, MANUFACTURED BY M/S INVENTOR PHARMA, KARACHI.
11	VOLUNTARY RECALL OF HUMAN ALBUMIN 20% BIOTEST (MANUFACTURED BY M/S BIOTEST AG, GMBH).

Case No. 01: MANUFACTURE & SALE OF SUB-STANDARD MELOVETZ INJECTION, REG. NO. 102021, BATCH NO. 2199017 MANUFACTURED BY M/S. VETZ PHAARMACEUTICALS (PVT.) LTD., KOTRI

Federal Inspector of Drugs-IV, DRAP, Karachi inspected the premises of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Q-1, S.I.T.E., Kotri, Sindh on 31-05-2021 and drawn sample for the of test/analysis on prescribed Form-3. Details are:

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	Remarks of CDL
01	Melovetz 10 Injection	102021	2199017	05-2021	04-2023	M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Q-1, S.I.T.E., Kotri, Sindh	Sub-Standard on the basis of pH.

02. Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under: -

S.No.	Test	Specification	Result	Reference
1	**Description**	Yellow colored oily solution in ambered glass vial.	Complies	BP Vet. 2020

2	**Identification**	The identification test must identify Meloxicam.	Complies	BP Vet. 2020
3	**pH**	7.5 to 9.1	**13.45%** **``Does not Comply.**	BP Vet. 2020
4	**Assay** Meloxicam (Lebel claim 10mg/ml)	95.0% to 105.0%	99.8%-Complies	BP Vet. 2020

Remarks: The sample is **"Sub-Standard"** quality under the Drugs Act, 1976.

03. FID submitted the case that firm was involved in manufacturing & selling of Substandard drug Melovetz 10 Injection batch No.2199017 and violated the section 23(1)(a)(v) of the Drugs Act 1976 and rules framed thereunder. FID recommended action under section 42 of the Drugs Act 1976. FID also forwarded the firm request of firm for appellate testing of the product "Melovet Injection"

04. Registration Board in its 317th meeting deferred the case and directed to present with the registration status of the product i.e. Melovetz 10 Injection (Registration No. 102021) including approved specification of finished product for consideration of firm's request in next meeting.

05. Registration status was asked from Registration Division and following points have been revealed:

- The product was registered with the name of Melovetz 10 Injection, Registration No. 102021vide letter No.F.7-1/2020-I&V-I (M-293) (Vet) dated 30-04-2020 in name of M/s Vetz Pharmaceuticals (Private) Limited, Kotri, Sindh.
- The finished product specifications of "Melovetz 10 Injection" are Innovator's Specification.
- Further registration letter condition xv shows that: "The innovator's specifications, however, are valid only till inclusion of the product in the official pharmacopoeia of reference countries as specified by the Registration Board"
- Since the product is available in official pharmacopoeia i.e. BP 2020, the tests performed as per BP 2020 by CDL Karachi.

06. The case has been deferred due to paucity of time in 320th meeting of the Board.

07. Registration Board in its 321st meeting decided to issue show cause notice under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Vetz Pharmaceuticals (Pvt) Ltd., Kotri and called them for a personal hearing before Registration Board.

08. In compliance with the decision of the Board, a show cause has been served to the firm vide office letter of even number dated 23-11-2022. M/s. Vetz Pharmaceuticals replied and reiterated same point mentioned earlier and desired to appear in person.

09. Firm has been called for a personal hearing.

Proceedings and Decision of 326th Meeting of Registration Board.

Mr. Muhammad Hanif, QC Manager has appeared before the Board on behalf of M/s Vetz Pharmaceuticals (Pvt) Ltd., Kotri. He submitted that the product was registered on innovator specification therefore they manufactured the product as per innovator specifications. Registration Board considered the pH range of Injection Melovetz as per manufacturer specification as well as pharmacopoeial specifications and the result of the test and after detailed discussion and thorough deliberations decided:

i. Suspension of Registration of Melovetz Injection, Registration No. 102021 under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.
ii. The firm was advised to follow the Pharmacopial specifications in compliance to the specification rules.
iii. Submission of RCA and CAPA by the firm.
iv. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT. During inspection the panel will also confirm the compliance to the specification rules.

Case No. 02: MANUFACTURE & SALE OF SUB-STANDARD BIOFEN SUSPENSION, REG. NO. 046094, BATCH NO. SP-167, MANUFACTURED BY M/S. BIO-LABS PRIVATE LIMITED, ISLAMABAD.

The Federal Inspector of Drugs-I, DRAP Islamabad sampled Biofen Suspension from the premises of M/s. Bio-Labs Pvt. Ltd. Islamabad dated 03-08-2021. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Remarks of CDL
Biofen Suspension	M/s. Bio-Labs (Private) Limited, Islamabad.	046094	SP-167	06/21	05/23	Substandard on the basis of Bio-Burden.

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Pink coloured suspension in ambered plastic bottles.	Complies.	Mfg. Specs.
2.	Identification	The identification test must identify Ibuprofen.	Complies.	USP 43
3.	**Bio-Burden (TAMC)**	**Not exceed 100 cfu/ml. (General chapter<61>.**	**1.5 x 103 cfu/ml Does not comply.**	**USP 43**
3.	pH	3.6 to 4.6	4.3-Complies	USP 43
4.	**Assay** Ibuprofen. (Label Claim 100mg/5ml)	90.0% to 110.0%	95.7%- Complies.	USP 43

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

02. M/s. Bio-Labs replied to FID dated 11-11-2021 requested for retesting to Appellate Lab NIH Islamabad.

03. As per decision of 313th meeting of Registration Board regarding appellate testing, firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 23-12-2021. M/s. Bio-Labs replied dated 06-01-2022 that no deviation has been observed during the testing of this batch. They mentioned in their OOS investigation report that:

"As per investigation of Stage-I and Stage-II and detailed review of BMR, the product is found ok with respect to bioburden test."

04. Federal Government Analyst, CDL, Karachi submitted OOS investigation. The result of sample does not comply to the specification. Final decision is OOS is valid.

05. Firm has directed to submit method of testing and records vide office letter of even number dated 08-09-2022. Firm replied dated 10-09-2022 that they provided SOP for Microbiological limit test and test reports. As per documents submitted by firm, they performed the test by pour plate method and there results were in defined limits.

06. Technical Evaluation of the case:

- The product was declared sub-standard on the basis of failure of Bio-Burden (TAMC) results.
- Firm claimed that they performed Bio-Buden test as per USP and results are as per specification. CDL performed test as per USP 43. The limit of test as per USP is "Not exceed 100 cfu/ml". Result of CDL is 1.5 x 103 cfu/ml.
- The method is based on visual inspection of the sample

07. Registration Board in its 321st Meeting did not accede the firm's request of appellate testing and decided to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Bio-Labs (Private) Limited, Islamabad and called them for personal hearing before Registration Board.

08. Decision was communicated to firm vide office letter of even numbers dated 23-11-2022. Ms. Bio-Labs, Islamabad has replied dated 01-12-2022 where they reproduced already mentioned point in their earlier replies and desired to appear in person.

09. Firm has been called for personal hearing.

Proceedings and Decision of 326th Meeting of Registration Board.

Mr. Muhammad Shahzad Rashid, Quality Assurance Manager, Mr. Haroon ur Rasheed, Quality Control Manager and Advocate Muhammad Shahrukh Sheikh have appeared before the Board on behalf of M/s Bio-Labs (Private) Limited, Islamabad. He submitted that the same product was also tested in different DTLs and the report was of standard quality and presented the report to the Board. On review of the report, it has been noted that the test of Bioburden was not performed by DTLs. Registration Board after detailed discussion and thorough deliberations decided:

i. Suspension of Registration of Biofen Suspension, Registration No. 046094 under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by panel with satisfactory report.
ii. Submission of RCA and CAPA by the firm.
iii. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.

Case No. 03: MANUFACTURE & SALE OF SUB-STANDARD TEMPRAMINE SUSPENSION, REG. NO. 011432, BATCH NO. 5TE049, 5TR131, 5TR052 AND 5TR057 MANUFACTURED BY M/S. W. WOODWARD PAKISTAN (PVT.) LTD., KARACHI.

A complaint has been received on Citizen Portal Pakistan regarding glass particles in Tempramine Syrup Batch no. STR057. Area FID Islamabad inspected the premises of Ms. Health Plus Distributors, Rawalpindi on 29-01-2021 and found that the distributor has voluntarily returned the stock of 12 batches of Tempramine Suspension on the direction of the firm as suspected sugar crystallization was observed.

02. Area FID, Karachi was requested vide office letter of even numbers dated 02-03-2023 to investigate the matter and probe out the root cause analysis of suspected glass particles in various batches of Tempramine suspension (WW0056, WW0057, 4TE009, 4TE014, 4TE019, 4TE054, 4TE059, 5TE049, 5TE051, 4TR007, 4TR008, 5TR052, 5TR130, 5TR057 and 5TR131) manufactured by Ms. W.Woodward Pakistan Ltd., Karachi, take samples of the suspected stock for the purpose of test/analysis and initiate legal action as per relevant provision of the Drugs Act, 1976.

03. FID Karachi inspected the premises of Ms. W.Woodward Pakistan Ltd., Karachi and took the samples of Tempramine suspension from the available returned stock on Form 3 for test/analysis, details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Result of CDL
Tempramine Suspension (Paracetamol 120mg/5ml, Chlorpheniramine maleate 1mg/5ml)	W. Woodwards (Pvt.) Ltd., Karachi	011432	5TE049	11-2020	11-2022	Sub-standard **Description- Does not comply.** Non homogenous suspension containing large white crystals of Paracetamol settled at the bottom of the bottle which do not redisperse even on rigorous shaking of the suspension. **Assay- Does not comply.**
-do-	-do-	-do-	5TR131	11-2020	11-2022	-do-

-do-	-do-	-do-	5TR052	05-2020	05-2022	-do-
-do-	-do-	-do-	5TR057	05-2020	05-2022	Sub-standard **Description- Does not comply.** Non homogenous suspension containing large white crystals of Paracetamol settled at the bottom of the bottle which do not redisperse even on rigorous shaking of the suspension

04. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said samples as **"Sub-Standard"** quality.

05. FID issued explanation letter to the firm in the light of test reports dated 29-06-2021 and 19-07-2021. M/s. Woodward's Pakistan (Pvt) Ltd., Karachi replied that after Citizen Portal complaint they voluntarily recalled the stock from distributor to avoid any risk of infiltration of any spurious drug in the market and to investigate the complaint. They further mentioned that all batches were checked physically and chemically from retention sample as well as recalled quantities. Retention sample were ok while testing recalled bottle samples only in few bottles crystal formation was observed which might be formed during logistics and transportation and cold temperature exposure in winter weather of December and January.

06. FID recommended that M/s. W.Woodward's Pakistan (Pvt) Ltd., Karachi has violated the section 23(1)(a)(v) of the Drugs Act 1976 and rules framed thereunder. The complete case is submitted with the recommendation for necessary action under Section 41 and Section 42 of Drug Act, 1976.

07. A show cause notice vide office letter of even numbers dated 21-11-2022 has been served to Ms. W. Woodward's Pakistan (Pvt) Ltd., Karachi after verification of names of responsible persons from Licensing Division.

08. Ms. W. Woodward's Pakistan (Pvt) Ltd., Karachi submitted their reply vide letter no nil dated 30-11-2022 that recall was carried out on voluntary basis and kept for further investigation and research studies at the company's warehouse. They further mentioned that QC retention samples of Batch no. 5TE049, 5TR131, 5TR052 AND 5TR057 were checked physically and chemically and results were found within the specification and free from any crystalline particles or sedimentation. However, the voluntary recalled stock were found to contain crystal formation in some of the bottles which might be formed during logistics and improper storage and exposure to cold climatic conditions in winter weather season of December and January.

09. Firm further mentioned that as they recalled the stock voluntarily and above mentioned facts; show cause notice may be withdrawn.

Comments of QA&LT Division:

10. In view of above-mentioned facts, crystals settled at the bottom of the bottle which do not redisperse even on rigorous shaking of the suspension may be due to issues during formulation development including but not limited to low viscosity and improper use of suspending agent to maintain redispersability.

11. Firm has been called for a personal hearing.

Proceedings and Decision of 326th Meeting of Registration Board.

Ms. Anjum Sibghat Ullah, Quality Operation Head and Israr Qadri, Senior Manager Production have appeared before the Board on behalf of M/s W. Woodward's Pakistan (Pvt) Ltd., Karachi. They submitted that they have recalled the stock voluntarily as the complaint was received prior to sampling the product. Further, they identified that mixing was the issue and they have bought hi speed sheer mixer to manufacture new batches and kept them for stability and found satisfactory results.

"Registration Board after detailed discussion and thorough deliberations decided:

i. Suspension of Registration of Tempramine Suspension (Registration No. 011432) under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till

verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by panel with satisfactory report; whichever is later.

ii. Submission of RCA and CAPA by the firm.

iii. Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.

Case No. 04: MANUFACTURE & SALE OF SUB-STANDARD PANTOLOON TABLET, REG. NO. 095091, BATCH NO. 5602 MANUFACTURED BY M/S. ROCK PHARMACEUTICAL LABORATORIES (PVT) LTD., RISALPUR.

The Federal Inspector of Drug Peshawar inspected the premises of M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd on 22-09-2021 on form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL Results
Pantoloon tablets	M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd., Risalpur.	095091	5602	12-2020	12-2022	Sub-Standard on the basis of Dissolution.

02. Results of CDL on the basis of which sample under reference has been declared as Substandard are reproduced as under:-

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Identification	The identification test must identify Pantoprazole Sodium	Complies.	USP 43
2.	Dissolution (Acid Stage)	**Stage 1**: Each unit is not less than Q=75% i.e. 75+5=80%. **Stage 2**: Average of 12 units (S1+S2) is equal to or greater than Q (75%) and no unit is less than Q-15% (75-15=60%). **Stage 3**: Average of 24 units (S1+S2+S3) is equal to or greater than Q (75%). Not more than 2 units are less than Q-15% (75-15=60%) and no unit is less than Q-25% (75-25=50%).	**Stage 1** Tablet no. / (%) age. 1 / 1.01 2 / 1.73 3 / 1.72 4 / 1.72 5 / 2.96 6 / 1.32 **Does not comply.**	USP 43
3.	**Assay** Pantoprazole. (Label Claim 20mg/tablet)	90.0% to 110.0%	107.9% Complies.	USP 43

Remarks: 1) *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

03. FID submitted the request of appellate testing of the product Pantoloon Tablets Batch no 5602.

04. Firm submitted the OOS investigation dated 14-03-2022 to FID. CDL submitted the response dated 26-08-2022. The final decision of investigation is OOS valid. The remarks of Lab Manager:

"As the buffer stage results are not within the specification of any three stages of dissolution defined by USP. Hence no need of re-test."

05. Technical Evaluation of the case:

i. The product is available in USP 43

ii. The product was declared substandard on dissolution.

iii. CDL performed the test as per USP 43 Dissolution Test 1 while firm performed on USP 43 Dissolution Test 2.

iv. The requirement /condition to performed Test 2 is:

"If the product complies with this test, the labelling indicates that the product meets USP Dissolution Test 2."

v. There is no specific test mentioned on certificate of analysis nor on pack of the product. Therefore, as per USP 43, Dissolution Test 1 is performed by CDL.

06. Registration Board in its 321st Meeting decided to send the sample of Pantoloon Tablets Batch no. 5602 to Appellate Lab for retesting of Dissolution test on which the sample was declared as Substandard.

07. In compliance to the decision, sample of Pantoloon Tablets Batch no. 5602 has been sent to Appellate Lab, NIH, Islamabad as per the decision of the Board. Sample of Pantoloon Tablets Batch no. 5602 was declared substandard by Appellate Lab NIH, Islamabad. Details of result are:

DISSOLUTION **Determined:**
TEST: (USP-Test 1)

Acid Stage	All the six tablet are within the limit.
Buffer Stage	All the six tablet deviated from the limit.
Limit:	
Acid Stage	Not more than 10% of the label amount of pantoprazole is dissolved.
Buffer Stage	Not less than 75% (Q) of the label amount of pantoprazole is dissolved.
	Does not comply with USP-39.
Remarks	Percentage release of drug among all six units tested at first level is found less than 80% (Q+5%) of the stated amount of pantoprazole. Moreover, drug release in all six units found less than Q-25% at S1 level. Therefore, Dissolution test is stopped at first stage.
Conclusion	The sample is of Sub-standard quality on the basis of test performed.

08. A show cause notice in light of Appellate Lab report has been issued to the firm vide office letter of even number dated 07-02-2023.

09. Ms. Rock Pharmaceutical Laboratories (Pvt) Ltd, Risalpur replied dated 23-02-2023 Briefly, they mentioned same stance as earlier. Further they submitted that they raised CAPA against this matter in the month of Feb 2023 and are working to further improve the formulation for the captioned product and taken few trials of the captioned product and will study and compare our development against innovator product "Protonix" 20mg tablets which is FDA approved. And will share results with QA&LT Division on successful completion and requested that following action (s) should not be initiated against us; i.e.

i. Cancellation / Suspension of Registration of product.
ii. Prosecution in Drug Court.
iii. Any other action the board may deem fit.

10. **Comments of QA&LT Division:**

i. Pantoloon Tablet was declared substandard on the basis of dissolution test. CDL performed the test as per USP 43 Dissolution Test 1 while firm performed on USP 43 Dissolution Test 2. The requirement /condition to performed Test 2 is:

"If the product complies with this test, the labelling indicates that the product meets USP Dissolution Test 2."

ii. While, there is no specific test mentioned on certificate of analysis nor on pack of the product. Therefore, as per USP 43, Dissolution Test 1 is performed by CDL as well as NIH.

iii. Further an advisory was also issued from Secretory Registration Board dated 06-02-2023 on subject "Compliance to Pharmacopoeial Specifications for Dissolution Test; the Board decided as:

"The rnanufacturer shall mention the dissolution test Number on the secondary packing/ unit carton of product for dissolution tests No 2,3 or 4 as per requirement of USP otherwise it would be presumed that dissolution test No.1 shall be performed on the finished product."

iv. The subject formulation is Enteric coated delayed release product in which dissolution test has to be conducted in two parts, First one is conducted and compliance at acid stage (P.H 1.2) and second is conducted and complied at buffer stage (P.H 6.8). It has been observed that beside the testing apparatus used for USP testing method, the product qualifies initial dissolution testing in acid stage, however failed in buffer stage in both reports of CDL and NIH. This indicates potential of error in product development phase as the substance release mechanism is attain

through PH depended enteric coating which in not fully compliant with buffer stage P.H.

v. Firm was also given opportunity of personal hearing but they did not submit request for personal hearing before the Board.

11. Firm has been called for personal hearing.

Proceedings and Decision of 326th Meeting of Registration Board.

Mr. Dilawar Bakhat, Quality Control Manager and Mr. Asad Iqbal, Production Manager have appeared before the Board on behalf of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Risalpur. They submitted that CAPA has been taken and they have worked on formulation improvement of the product.

"Registration Board after detailed discussion and thorough deliberations, considering the facts of the case and considering the subsequent offence of failure of another sample of same product vide CDL report No. IP-6-22-0000110 dated 09-09-2022 and considering the stance of firm; Board decided to cancel Registration of Pantoloon Tablets, Registration No. 095091 of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Risalpur under section 42 of the Drugs Act, 1976 and rules framed thereunder."

Case No. 05: MANUFACTURE & SALE OF SUB-STANDARD PROTONIX 40MG TABLETS, BATCH NO. 052 & 069 BY M/S WILSHIRE LABORATORIES (PVT.) LTD., LAHORE.

The Federal Inspector of Drugs, Karachi visited the premises of M/s Marhaba Medicos, Shop No. 51, Bismillah Market, near New Sabzi Mandi Super Highway, Karachi on 25-04-18 and took sample of Protonix 40mg Tablets, Batch No.052 on form-3. Details are

S. No.	Name of Drug	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Reason of Sub-Standard Product
01	Protonix 40mg Tablet	030041	**052**	09-17	08-20	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore	Dissolution test does not comply.

02. The Federal Government Analyst, CDL, Karachi declared the sample as of Sub-standard quality **on the basis of dissolution** vide test/analysis report R.KQ.310/2018. Details of report are:

Description:	*Yellow colored, circular shaped enteric coated tablets.*
Identification:	*Pantoprazole Sodium identified.*
Dissolution test:	***Does not comply.***
Uniformity of dosage unit	
By Weight Variation:	*Complies.*
Assay for Pantoprazole Sodium:	
Determined amount/tablet:	*38.2609mg*
Stated amount/tablet:	*40mg*
Percentage:	*95.7%*
Limits:	*90.0% to 110.0% Complies.*

Remarks: *The sample is of* ***"Substandard"*** *quality under the Drugs Act, 1976.*

03. Area FID, Karachi served an explanation letter to M/s Wilshire Laboratories (Pvt.) Ltd, Lahore dated 26-06-2018. M/s Wilshire Laboratories (Pvt.) Ltd, Lahore submitted their reply vide letter wherein *they have stated that*

"They received the sealed portion of their product Protonix 40mg Tablets (Samples quantity of 30 tablets) while Batch No/Mfg Date/Exp Date was not visible on sample pack. We also receive the sample after 41 days after picking the sample which is violation of Section 19 (3) of the Drugs Act 1976. As guidelines of the Drugs Act 1976 were not followed which is illegal and the said procedure is null and void in the eyes of law. The sample dispatched to us remained in transit during very hot months of May and June while no temperature and humidity conditions were maintained.

Storage conditions are not mentioned on the report where the sample was stored after receipt and we fail to understand as the sample remained untested for 54 days. We had provided reference standard to CDL but we are not sure whether our provided reference standard was used for testing or CDL arranged reference standard from some other source because USP 40 method was used. So, USP reference standard must have been used. Please provide a copy of reference standard of Pantoprazole USP. As per USP method of testing, 68 tablets are required while the sample sent to CDL, Karachi contain 30 tablets so how the required tests can be performed with provided sample."

04**.** Show cause notice has been issued to the technical staff/management of the firm vide letter No. 03-49/2018-(QC) dated 06-03-2019.

05. Firm's representatives had been appeared in 289th Meeting of Registration Board dated 16-05-2019 and re-iterated points already submitted in showcause reply and the firm requested for retesting of drug product. Registration Board after hearing them decided that the Board's portion of the sample shall be retested from appellate laboratory, NIH, Islamabad.

06. The Appellate Laboratory, NIH, Islamabad declared the said sample as Misbranded and Substandard quality (on the basis of dissolution) vide test report No.04-M/2019

07. Show cause notice has been served to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-49/2018-(QC) dated 12-11-2019.

08. M/s Wilshire Laboratories (Pvt.) Ltd., Lahore vide reference No.WL/OC/S-344 submitted their reply that We have provided method of testing with "Manufacturer Specification" to NIH but we are surprised to learn that our product has been tested on USP-39. Also raised some other points which were not justified and requested to withdraw the show cause.

09. Firm's representatives had been appeared before the Board in 293rd meeting of Registration Board dated 08-01-2019 and stated that they still have concerns on the analytical method of NIH, Islamabad. Furthermore, they have made necessary improvements and shifted their product from manufacturer's specifications to Pharmacopoeial specifications. They further requested to analyze their product from individual laboratory.

10. Board after detailed discussion and deliberations considering the test reports of CDL & Appellate Lab NIH, Islamabad unanimously decided as under:

- **i.** Suspension of the Registration of the said product for six (06) months or till the verification of root cause analysis and satisfactory report by the panel whichever is later.
- **ii.** Corrective and preventive action (CAPA) by the firm and product development data.
- **iii.** Product Specific Inspection including verification of product development data and confirmation of CAPA by the following panel:
  - Mr. Iftikhar Ahmad Member Registration Board.
  - Area Federal Inspector of Drugs.
  - Hafiz Ahsan AD, PEC.

11. Decision letter was sent vide office letter of even numbers dated 21-04-2020.

12. FID, DRAP, Lahore has submitted the PSI report of M/s. Wilshire Labs (Pvt.) Ltd., Lahore. The inspection was conducted for verification of root cause analysis, corrective and preventive action (CAPA) and product development data of their product Protonix 40mg Tablet containing Pantoprazole sodium sesquihydrate.

Conclusion:

Based on the inspection proceedings, such as verification of documents, interaction with management e.t.c the panel concludes that the company has not given root cause analysis and rectified their dissolution problem through product development process. The firm only shifted their testing method from Mfg spec to UPS. However, the management made commitment and also agreed to make necessary improvements in procedures.

Recommendation:

Keeping in view the above observations the panel could not verify the product development process and root cause analysis conducted by the firm

at this stage. However, the final conclusion would be based upon the test report results received from the Central Drugs Laboratory, Karachi.
Hence, ***the panel recommend that the decision of the Drug Registration Board for suspension of registration of Protonix 40mg Tablets may remain intact.***

13. PSI report was presented in 308th meeting of Registration Board. The Board after thorough deliberations, considering the facts of the case, report submitted by the FID, DRAP, Lahore decided as
    i. The suspension of registration of Protonix 40mg Tablet remain intact.
    ii. The Comparative Dissolution Profile of the product with innovator's product will be submitted by the firm for consideration of the Board.
14. The decision has been communicated to the firm vide office letter of even numbers dated 08-09-2021.
15. M/s. Wilshire Labs (Pvt.) Ltd., Lahore vide Ref # WL/OC/S-597 dated 14-09-2021submitted that they used Dissolution Test 2 for testing of our product. They also requested for personal hearing.
16. The Board in its 313th meeting after thorough deliberations, considering the facts of the case, decided to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Wilshire Labs (Pvt.) Ltd., Lahore and called them for personal hearing before Registration Board.
17. Firm's representatives appeared before the Board in 316th meeting. The Board after considering the facts of the case and after thorough deliberations decided as follows:
    i) The sample of Protonix 40mg Batch No. 069 shall be sent for Appellate testing as per USP specification (Dissolution Test-Type 2)
    ii) Firm shall develop product as per guidelines approved in 293rd meeting and will share data with QA Division.
    iii) Registration of product 'Protonix 40mg Tablet' (Reg# 030041) shall remain suspended till compliance of both above points.
18. The decision of the Board has been communicated to firm and the Board's portion submitted in Appellate Lab NIH as per decision vide office letter of even numbers dated 27-02-2022.
19. Test report of the sample has been received from Appellate Lab NIH where in it is concluded as:
    "The sample is of Sub-standard quality on the basis of test performed."

Details of failed samples:

Name:	Protonix 40mg Tablet	Protonix 40mg Tablet
Composition:	Each tablet contain 40mg Pantoprazole	Each tablet contain 40mg Pantoprazole
Registration No:	030041	030041
Batch No:	**052**	**069**
Manufacturing Date:	09-17	Jan. 2020
Expiry Date:	08-20	Jan. 2023
Manufactured By:	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore
Result of CDL	Substandard	Substandard
Result of Appellate Lab	**Substandard**	**Substandard**

20. The case has been presented in 323rd meeting of Registration Board, Board after detailed deliberation decide to issue show cause notice to the firm on manufacturing and sale of substandard Protonix 40mg Tablets, Batch no. 052 and 069 and provide personal hearing under section 42 of the Drugs Act, 1976 and rules framed thereunder.
21. Decision has been communicated vide letter of even number dated 23-01-2023.
22. Firm has replied dated 01-02-2023, they mentioned same stance already communicated vide their earlier letters. n their reply they have stated that " In report of (NIH) , the acid stage performance of dissolution is missing and release profile is not calculated quantitatively at this stage .Without acid stage results the overall drug releasing behavior of delayed release product cannot be concluded as in interpretation of dissolution of delayed released products USP<711> it is clearly stated as ,*the quality (Q)specified in the*

monograph is the total amount of active ingredients dissolved in the both acid stage and buffer stage ,expressed as percentage of the labeled content.

23. They have also pointed out calculation errors in NIH report and mentioned that they have further improved their formulation by working on core and seal coating which control mechanism of delayed release in tablet and has performed Comparative dissolution profile (CDP) with comparator brand Protium 40 mg of M/s Abbott labs.

24. Firm has requested to grant permission to proceed manufacturing of protonix tablet 40 mg with revised USFDA approved formulation and accept their proposal of collection of samples from the manufacturing premises during production of commercial batch.

Comments of QA&LT Division:

25. Firm has misquoted the interpretation and calculation of Q value form general chapter 711 of USP, under the heading of delayed release dosage form, it is stated that "***unless otherwise specified in the individual monograph, the requirements are met if the quantity of active ingredients dissolved from the units tested conforms to acceptance table 4. continue testing through the three levels unless the results of both stages conforms at an earlier level. the value of Q in acceptance table 4 is 75 % dissolved unless otherwise specified in the individual monograph. The quantity, Q, specified in the individual monograph ,is the total amount of active ingredient dissolved in both the acid stage and buffer stage ,expressed as percentage of the labeled content .The 5 %,15% and 25 % valve in acceptance table 4 are the percentage of the labled contents so that these values and Q are in the same terms .***

Acceptance table 4

Level	Number tested	Criteria
B1	6	Each unit is NLT Q+5 %
B2	6	Average of 12 units (B1+B2) is ≥ Q, and no unit is < Q-15
B3	12	Average of 24 units (B1+B2+B3) is ≥ Q, NMT 2 units are < Q-15, and no unit is < Q-25.

26. Moreover, the specific monograph of Pantoprazole sodium delayed release tablet in USP clearly mentioned qualification of both acid and buffer stage mentioned separate acceptance criteria for Acid stage and buffer stage and under;
Tolerance for Acid stage is: NMT 10 % of labeled amount of pantoprazole is dissolved
Tolerance for Buffer stage is: NLT 75%(Q) of the labeled amount of pantoprazole is dissolved.

27. Firm has been called for a personal hearing.

Proceedings and Decision of 326th Meeting of Registration Board.

Mr. Akhter Hussain, Head of Quality Operation, and Mr. Ahsan Sabir, Manager, Quality Control and Research and Development have appeared before the Board on behalf of M/s Wilshire Laboratories (Pvt.) Ltd, Lahore. They submitted that they have worked on product development and manufactured two trial batches in April 2022, kept them for stability, maintained the record and results will be provided to Board if required.

"Registration Board after detailed discussion and thorough deliberations considering the facts of the case as two batches of the product had been declared substandard from CDL and Appellate Lab *NIH; Board decided to cancel Registration of Protonix Tablets; Registration No. 030041 of M/s Wilshire Laboratories (Pvt.) Ltd, Lahore under section 42 of the Drugs Act, 1976 and rules framed thereunder."*

Case No. 06: **MANUFACTURE & SALE OF SUBSTANDARD KLEVRA ORAL SOLUTION, BATCH NO. 0N152, MANUFACTURED BY M/S. PHARMEVO (PVT.) LTD. KARACHI.**

Test/analysis report No.KQ.57/2021 dated 20th March, 2021, from the Federal Government Analyst, CDL, Karachi received on 29-04-2021. Wherein, the Federal Government Analyst has declared sample of Klevra Oral Solution as of **"Sub-standard quality"**. Details are:

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	CDL Results
01	Klevra Oral Solution (Levetiracetam)	066831	0N152	Dec. 2020	Dec. 2022	M/s. PharmEvo (Pvt.) Ltd. Karachi	Sub-Standard on the basis of pH.

Results of CDL on the basis of which sample under reference has been declared as Substandard quality are reproduced as under:-

S.No.	Test	Specification	Result	Reference
1.	Description	Clear, and transparent solution having cherry flavor.	Complies.	Mfg. Specs.
2.	Identification	The identification test must identify Levetiracetam.	Complies	USP 43
3.	pH	4.8 to 6.3	**4.52** **Does not Comply.**	USP 43
4.	**Assay** Levetiracetam. (Lebel claim 500mg/5ml)	90.0% to 110.0%	98.4%- Complies.	USP 43

Note:- The product is included in USP 32 now; therefore, PharmEvo Specs. Should be removed as printed on the label.

Remarks: *The sample is **"Sub-Standard"** under the Drugs Act, 1976.*

2. FID has been asked to submit complete case vide office letter of even number dated 04-05-2021. The recall alert to manufacturer issued dated 04-05-2021.

3. M/s. PharmEvo (Private) Limited, Karachi submitted that the product is registered with Manufacturer Specification (MS) while CDL declared the product as of substandard quality on USP specification. They further said that as DRAP has under circular no. F.3-5/2020-I&VII (M-297) dated 27-01-2021; the board allowed 6-month time for implementation of the decision. They also requested to withdrawn the Drug recall from website of DRAP.

4. Registration division confirmed that product is registered on MS and renewed on 06-08-2020. Firm has not applied for change of specification of subject drug till date. Further, Firm has been manufacturing product under consideration with manufacturer's specification despite of inclusion of said formulation in USP which is against the decision of Registration Board and Central Licensing Board communicated vide letter no. F.3-2/2006-Reg-II-South (M-197) dated 05-06-2006 where in it was decided that firms may adopt their own specifications for the drugs which are not included in the official Pharmacopeias, till the inclusion of these formulations in the official pharmacopeias listed in Section-3 of Drug Act 1976.

5. Furthermore, letter No.F.3-5/2020-I&VII(M-297) dated 27-01-2021 is issued in the context of labeling of specification due to which DTLs/QCLs declaring the products as "Misbranded" after deliberations/ discussion regarding the matter and does not apply if product is declared as Sub-Standard on being tested on official Pharmacopeia.

6. A letter has been issued to firm w.r.t. above decisions dated 02-08-2022.

7. M/s. PharmEvo Private Limited, Karachi submitted their reply in response to office letter dated 02-08-2021 wherein firm has mentioned that:

"The instructions of MOH/DRAP with regards to pharmacopoeial specifications stand suspended and have been held in abeyance by DRAP till January 26, 2022 vide notification circular No. F.3-5/2020-I&VII (M-297) dated 26-07-2021."

8. They further requested to withdraw the Medical product alert from DRAP website.

9. FID, DRAP, Karachi submitted the case details and recommended that:

"As per Federal Government Analyst, CDL Karachi test report No KQ-57/2021 dated 20-04-2021, M/s. PharmEvo Private Limited, Karachi violated the Section 23(1)(a)(v) of the Drugs Act 1976 and rules framed there under."

10 The case has been submitted for consideration in light of above-mentioned decision of Registration Board.

Proceedings and Decision of 317th Meeting of Registration Board

11. Registration Board deferred the case and directed to present with the registration status of the product i.e. Klevra Oral Solution (Registration No. 066831) including approved specification of finished product for consideration of firm's request in next meeting.

12. Registration status was asked from Registration Division and following points have been revealed:

- The product was initially registered with the name of Equip Oral Solution Reg No. 066831vide letter No.F.3-6/2010 Reg-II (M-227) dated 08-10-2010 in name of M/s PharmEvo Pvt Limited Karachi.
- The brand name was changed to Klevera Oral Solution vide letter No.F.6-1/2011-Reg-II dated 10-02-2011.
- The finished product specifications of "Klevra Oral Solution" were changed from "Manufacturer's Specification" to "USP Specification" vide approval issued dated 19-11-2021
- The renewal for year 2015 was received on 19.08.2015 and for year 2020 was received on 06.08.2020. Both of aforesaid renewals are within time w.r.t date of registration.

Decision of 320th meeting of Registration Board

13. The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

14. The Registration Board after discussion and by considering the facts of the case decided to issue show cause notice under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. PharmEvo Private Limited, Karachi and called them for personal hearing before Registration Board.

15. Decision of the Board has been communicated vide office letter of even number dated 23-11-2022.

16. Firm submitted reply vide letter no nil dated 15-12-2022, they submitted their already mentioned points and said that manufacturer specification was mentioned on the pack of product while CDL declared the product substandard. Further they informed that they applied for change of registered specification and granted in November 2021. They further submitted that we hope the allegations leveled in the letter/notice under reply will be retracted and recalled and the needful will be done to negate the wrongful declaration made in the stated test report of CDL Karachi.

Comments of QA&LT Division:

17. Product has been registered dated 08-10-2010. The substandard batch no. 0N152 of Klevra oral solution was manufactured in December 2020 while the product's monograph i.e. Levetiracetam oral solution was already included in USP. Further, the matter of extension in compliance with pharmacopeial specifications was discussed in 297th meeting held on 12-14 January 2021 (after the manufacture of said batch) on reference sent by various forums viz DTL Faisalabad, PPMA, Pharma Bureau.

18. Firm has applied for change of specification after the substandard report and got approval in November 2021.

19. In view of above narrated facts, firm has to adapt the pharmacopeial specifications as soon as inclusion of the monograph in official pharmacopeia, in accordance with Drug Specification Rules 1978 and as per letter no. F.3-2/2006-Reg-II-South (M-197) dated 05-06-2006.

20. As change of specification has been granted, FID may be asked to take sample from new batch to verify the specification of the product.

21. Firm has been called for personal hearing.

Proceedings and Decision of 326th Meeting of Registration Board.

Mr. S. Safdar Abbas, Manager Regulatory and Mr. Khurram Anis, General Manager, Quality Operation have appeared before the Board on behalf of M/s PharmEvo Private Limited, Karachi. They submitted that the product was on manufacture specification and they applied in June 2021 for a change of specification and approved USP specification has also been granted for the product "Klevra oral solution" in November 2021. After that new batch has been manufactured as per USP specifications.

Registration Board after detailed discussion and thorough deliberations decided to issue a warning letter to M/s. PharmEvo Private Limited, Karachi in instant case, with directions to be more vigilant in future. Further, Board also directed the firm to review product specifications of their all registered products and adapt pharmacopoeial specifications where required, in accordance with Drug Specification Rules 1978 on priority basis.

Case No. 07: SUBSTANDARD 25% DEXTROSE INFUSION B. NO. A042C21 MANUFACTURED BY M/S. OTSUKA PAKISTAN LTD., HUB, BALOCHISTAN.

Federal Government Analyst CDL Karachi vide test report No. F. 5-3(K)/2021-CDL/S-1468 dated 03-12-2021 informed that sample of product "25% Dextrose Infusion" Batch No. A042C21 (Mfg. date 31-03-2021, Exp date 30-03-2024) sent to CDL Karachi by FID-II Karachi has been declared as of substandard quality on the basis on non-compliance of pH specifications. Details of the test report are given as under:

S. No.	Test	Acceptance Criteria	Result	Reference
1.	Identification	The identification test must identify Glucose (Dextrose)	Complies	BP 2020
2.	pH	3.5 to 6.5	**2.73 – Does not comply**	BP 2020
3.	Bacterial Sterility	Must be sterile	Complies	BP 2020
4.	Endotoxin	The Endotoxin limit concentration is 0.25 IU/ml	Complies	BP 2020
5.	Assay Glucose (Dextrose), (Label claim 250mg/ml)	95.0% to 105.0%	96.80% Complies	BP 2020

02. FID-III Karachi vide letter No. F. ARS-19-25/2021-FID-III (K) dated 28-12-2021 forwarded the request of M/s. Otsuka Pakistan, Hub dated 23-12-2021 for appellate testing of their product namely "25% Dextrsoe Infusion" batch No. A042C21 declared substandard by CDL Karachi on 03-12-2021.

03. Registration Board in its 313th meeting decided to fulfill the codal formalities. Therefore, in the light of decision of Registration Board, a vide letter No. F. 03-48/2021-QC dated 27-01-2021 issued to M/s. Otsuka Pakistan, and to FGA CDL Karachi for submission of OOS investigation and complete testing record of report vide No. F. 5-3(K)/2021-CDL-S-1486 dated 03-12-2021.

Technical evaluation of OOS report by QC section:

05. M/s. Otsuka Pakistan Limited, Hub vide letter dated 15-02-2022 and CDL Karachi vide letter No.1-1/2013-SRK/CDL/-1069 dated 15-03-2022 provided OOS investigation. Comparison is given as under:

S.	**Laboratory**	**Test Performed**	**Results**	**Standard Value**	**Remarks**
01	CDL Karachi	pH (BP 2020)	2.73	3.5 – 6.5	-
02	M/s Otsuka	pH (BP)	At the time of batch release: 5.38 **Retesting:** Sample 1: - 3.58 Sample 2: - 3.54 Sample 3:- 3.58	-do-	The results of retesting performed by the firm show a decline in pH value from 5.38 to 3.58 over a period on 10 months. Moreover, the value 3.58 is also very close to the lower acceptance criteria i.e. 3.5

06. The case has been deferred due to paucity of time in 320th meeting

In view of decision of 320th meeting, they have been called for personal hearing.

07. Decision of 321st meeting Keeping in view position narrated above, the Board did not accede the firm's request of appellate testing and decided to issue show cause notice and called them for personal hearing before Registration Board.

08. In compliance to the decision of RB show cause was issued to firm vide letter No. 03-45/2022-QC dated 21-Nov-22 to which the firm replied and again called for appellate testing of their product namely "25% Dextrose Infusion" batch No. A042C21 declared substandard by CDL Karachi on 03-12-2021 and briefed that due to temperature issue pH decreased but still remained within limits and submitted CAPA in which they manufacture 3 trial batches i.e bulk manufacturing

at 80&100^{o} & with addition of stabilizers that is showing stability after 8 months passed and they are going to change its label with indication "*Store below 25 degrees centigrade*".

09. Case was discussed in 324th meeting of Registration Board and decided as under:
Keeping in view position of firm narrated above, the Board decided that

i) Risk based sampling of all the batches of said formulations will be done.
i) Call the firm for personal hearing under section 42 as they are found to have contravened provision of this act.
ii) Product registration of 25% Dextrose Infusion Mfg by M/s. Otsuka Pakistan ltd., hub, Baluchistan will remain suspended till personal hearing before next meeting of Registration Board and decision by the board.

10. Decision was communicated to firm vide letter dated 03-04-2023-QC dated 08-03-2023 and called for personal hearing.

Submitted for consideration by board

Proceedings and Decision of 326th Meeting of Registration Board.

Mr Attique Rahman (Head of Quality Operations) along with Counsel, Mr Adv Rashid Mureed appeared before the Board for Personal hearing. They pleaded that they have already lodged appeal against the decision of 324th meeting of DRB in appellate board as their request for appellant testing was not acceded and their registration was suspended without giving an opportunity of personal hearing. The Board after considering the facts of the case and thorough deliberations decided as follows:

"As firm has challenged the decision of 324th meeting of DRB before appellate board under section 9 of the Drugs Act, 1976, as remedial quasi-judicial forum therefore the proceeding of registration board shall remain suspended till finalization and decision of appellate board".

Case No. 08: MISBRANDED BALINGO INJECTION B. NO. BL-1417 MANUFACTURED BY M/S. BAJWA PHARMACEUTICALS (PVT.) LTD., 36-KM OFF G.T ROAD LAHORE – QCB ISLAMABAD CASE.

Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/725 dated 22-02-2022 forwarded the case of manufacturing of Misbranded Injection Balingo 10ml (Lignocaine) Batch No. BL-1417 Manufactured by M/s. Bajwa Pharmaceuticals, Lahore. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of District Population Welfare office G-9 markaz Islamabad drew samples of injection Balingo 10ml Batch No. BL-1417 manufactured by M/s. Bajwa Pharmaceuticals Lahore for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Injection Balingo 10ml as "Misbranded" under clause (vi) of subsection (s) of section 3 of the Drugs Act 1976.
iii. The accused were called before Quality Control Board Islamabad in its 50th meeting for personal hearing.

02. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

"The Board was briefed about the facts of the case as per record by the Secretary. The representative of firm alongwith supplier appeared before the Board and informed that the labeling error was rectified and replacement to the Department was also made. The members also questioned the representative about the existence of Quality Assurance arrangements of the firm. The Board considered the facts available on record and after discussion decided to refer the case to Drug Registration Board for cancellation of drug registration of i.e. Inj. Balingo 10ml of M/s Bajwa Pharmaceuticals, Lahore after fulfillment of all legal/codal formalities in this regard"

03. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Injection Balingo 10ml, Reg. No. 078952 manufactured by M/s. Bajwa Pharmaceuticals Lahore.

Proceedings and Decision of 320th meeting:

The case has been deferred due to paucity of time.

Proceedings and Decision of 321st Meeting of Registration Board.

Registration Board after discussion, considering the facts of the case decided:

"To issue show cause notice to M/s. Bajwa Pharmaceuticals Lahore for manufacturing and sale of Misbranded Injection Balingo 10ml (Lignocaine) Batch No. BL-1417" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."

04. Firm replied vide letter no BPL/DRAP/BL/23/01/001 dated 17-01-2023 in response to Show-Cause notice vide office letter of even numbers 03-45/2022-QC dated 06-01-2023 that they had rectified their label as per Labeling and Packing Rules 1986 and submitted the rectified label in 50th meeting of Quality Control Board Islamabad dated, 30-12-2021. Kindly give us a chance to we will strictly follow labelling and packing rules 1986.

05 Letter has been issued to firm dated 08-03-2023 for personal hearing.

Submitted for consideration by Board

Proceedings and Decision of 326th Meeting of Registration Board.

Mr Farhat Munawar Bajwa (C.E.O) appeared before the Board for Personal hearing. He pleaded that he had rectified their label as per Labeling and Packing Rules 1986 and also presented the rectified label in 50th meeting of Quality Control Board Islamabad dated, 30-12-2021.

The Board after thorough deliberations and considering the facts of the case that product was declared misbranded of the basis of not mentioning product specification on unit carton however remaining quality attributes of product as per DTL Rawalpindi report are satisfactory, Therefore Board decided to:

i) issue warning letter to M/s. Bajwa Pharmaceuticals, Lahore to remain vigilant in future in this regard.

ii) direct M/s Bajwa Pharmaceuticals, Lahore to review and check product specifications as per pharmacopoeia, are mentioned on all of their registered products and submit report in QA/LT division.

iii) Include M/s Bajwa Pharmaceutical, Lahore in risk based inspection as per schedule of QA/LT division.

APPELLATE TESTING

Case No. 09: MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION BATCH NO. W-20017 & W-20024, MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.

The Federal Inspector of Drug, DRAP, Karachi visited the premises of M/s Mediate Pharmaceutical (Pvt.) Ltd., Karachi on 14-04-2021 wherein following samples along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	CDL remarks
Hitaxime 1gm Injection (vial) Cefotaxime	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044109	V-20059	11-2020	11-2022	Standard.
Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20017	07-2020	07-2023	Substandard on the basis of Bacterial endotoxin.
Hilixophin 500mg Injection (vial) Ceftriaxone	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044105	V-20085	12-2020	12-2022	Standard.
Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20024	12-2020	12-2023	Substandard on the basis of Bacterial endotoxin.

02. Results of CDL on the basis of which sample under reference has been declared as Substandard are reproduced as under:-

i. Reports No. KQ.91/2021:

(STERILE WATER FOR INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Clear sterile water, free from visible particles, preserved in single dose glass or plastic container.	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	**Bacterial Endotoxin**	**Less than 0.25 EU per ml.**	**Does not comply.**	**USP 43**

(HITAXIME 1GM INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Offwhite powder in clear glass vial	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Cefotaxime Sodium.	Complies.	USP 43
3.	pH	4.5 to 6.5	Complies.	USP 43
4.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
5.	Bacterial Endotoxin	Not more than 0.20 EU per mg.	Complies.	USP 43
6.	Assay Cefotaxime (label claim 1gm/vial)	90.0% to 115.0%	105.0% complies	USP 43

NOTE: Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

ii. Reports No. KQ.92/2021:

(STERILE WATER FOR INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Clear sterile water, free from visible particles, preserved in single dose glass or plastic container.	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	Bacterial Endotoxin	Less than 0.25 EU per ml.	**Does not comply.**	USP 43

(HILIXOPHIN 500MG INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Off white powder in clear glass vial.	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Ceftriaxone Sodium.	Complies.	USP 43
3.	pH	6.0 to 8.0	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	Bacterial Endotoxin	Not more than 0.20 EU per mg.	Complies.	USP 43
6.	Assay Ceftriaxone. (label claim 500mg/vial)	90.0% to 115.0%	100.3% complies	USP 43

NOTE: Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

03. FID, DRAP, Karachi informed that the firm has requested for retesting. The firm stated that:

"[…] we are requesting you to retest Bacterial Endotoxin test of both WFI injections, for this purpose we retest samples in our QC Dept. with three different kits and find results as given below:

Test performed	***Bioendo***	***Lonza***	***Cape-Cod***
Bulk sample	*Fail*	*Pass*	*Pass*
Sample after autoclave	*Fail*	*Pass*	*Pass*
W-20017	*Fail*	*Pass*	*Pass*
GSK WFI SPW9/1 (02-2018)	*Fail*	*Pass*	*Pass*

04. As per decision of 313th meeting of Registration Board regarding appellate testing, firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 26-01-2022.

05. M/s. Mediate Pharmaceutical Pvt Ltd., Karachi replied that they have conducted investigation but found no fail results. Firm has mentioned that they cross checked the recalled product and QC retention samples and performed bacterial endotoxin test by using three different kits out of which results of Bioendo endotoxin kit were not satisfactory. Details are:

S.no	**Reagent used**	**Results**
Lonza Endotoxin Kit		
1	Lysate reagent	Satisfactory
2	Control standard endotoxin	Satisfactory
3	Lal reagent water	Satisfactory
Cape code Endotoxin Kit		
4	Lysate reagent	Satisfactory
5	Control standard endotoxin	Satisfactory
6	Lal reagent water	Satisfactory
Bioendo Endotoxin Kit		
7	Lysate reagent	Un-satisfactory
8	Control standard endotoxin	Un-satisfactory
9	Lal reagent water	Un-satisfactory

06. While CDL, Karachi submitted OOS investigation, the result was OOS is confirmed.

Technical Evaluation of the case:

- The product was declared sub-standard on the basis of results of Bacterial endotoxin.
- Endotoxin test performed by Gel Clot method both by firm and CDL as given in USP 43.
- The method is based on visual inspection of the sample after incubation for presence of gel or otherwise.

Proceedings and Decision of 326th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi and CDL, DRAP Karachi was presented before Registration Board.

After Through discussion about (OOS) Investigation report submitted by the firm and deliberation the case in detail and decided

1. not to accede the firm's request for appellate testing of this product and
2. to issue show cause notice under Section 42 of the Drugs Act, 1976 and rules framed thereunder, for suspension / cancellation of product Sterile water for injection (ampoule) Registration # 053244 manufactured by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi and called for personal hearing before Registration Board in this instant case.

ROUTINE CASES

CASE NO. 10: MANUFACTURE & SALE OF SUBSTANDARD PARAPALS INFUSION, BATCH NO. LI-100, LI-101 & LI-102, MANUFACTURED BY M/S INVENTOR PHARMA, KARACHI.

The Federal Inspector of Drugs, DRAP inspected the premises of M/s. Sindh Government Hospital, UP Mor, New Karachi on 22-10-2020 wherein, following samples of drugs with apparent discoloration in the solution of Parapals Infusion were taken on Form-3 for the purpose of test/analysis and remaining stock ordered Not to Dispose of on Form-1 under Section 18(1) of the Drugs Act, 1976.

S. No.	Name of Drug	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Reason of Adulterated and Sub-Standard Product (Initial Report)	Reason of Adulterated and Sub-Standard Product (Final Report)
01	Parapals IV Infusion 100ml (R. No. 088360)	088360	**LI-101**	03/2020	03/2022	M/s. Inventor Pharma, Karachi	Deep brown colored solution containing very large fiber particles. Does not Comply.	-Deep brown colored solution- Does not comply. -pH does not comply. -Bacterial sterility- Does not Comply.
02	-do-	-do-	**LI-100**	-do-	-do-	-do-	-do-	Deep brown colored solution- Does not comply. -Bacterial sterility- Does not Comply.
03	-do-	-do-	**LI-102**	-do-	-do-	-do-	-do-	-Deep brown colored solution- Does not comply. -Bacterial sterility- Does not Comply.

02. FID served a number of explanation letters but no reply from the firm is received yet.

03. FID submitted that M/s. Inventor Pharma, Karachi has violated the Section 23(1) (a) (iv) and 23(1) (a) (v) of Drugs Act, 1976 in view of non-positive attitude of the firm towards GMP compliances and product failure ratio. FID recommended that:

i. Registration of the product **Parapals Infusion Reg. No. 088360** may kindly be

suspended/cancelled for a certain period being a non-safer drug and all other drugs being manufactured at their premises may kindly be reviewed after detailed panel GMP inspection by the panel.

ii. The names of technical persons may be obtained from Licensing Division, DRAP, Islamabad as firm did not provided the names despite of several letters.

04. A show cause notice has been issued vide office letter of even number dated 05-10-2021 to the firm. No reply has been received so far.

05. Registration Board in its 316th meeting of Registration Board heard the firm's representative and after deliberated the facts of the case in detail decided:

i. Suspension of the Registration of Parapals Infusion (Registration No. 088360) for six months or submission of product development data, root cause analysis along with CAPA; which is later.

ii. Product Specific Inspection shall be conducted by following panel:
   a. Mr. Rafeeq Alam
   b. Mr. Affan Ali

06. Panel has been revised vide office letter of even number dated 25-11-2023, PSI was conducted dated 10-01-2023. Conclusion of the report reproduced as:

"Based on the above stated facts the panel concluded that failure was because of the improper Nitrogen Gas supply during filling operations which could have caused oxidation resulting blackish of solution. The firm has taken CAPA and manufactured more three trial batches of said product and found satisfactory results of ongoing stability studies thus recommended the resumption of production of Parapals Infusion 1000mg/100ml Registration Number 088360 after taking fresh sample from 1st commercial batch for test/analysis by CDL Karachi on the expense of manufacturer and then firm will sell the product after standard CDL report."

Comments of QA&LT Division:

07. Though the panel recommended the resumption of registration of Parapal Infusion relying upon the RCA & CAPA submitted by the firm. However, it is noted that in RCA the firm only focused on adulteration and did not address the failure of product on the basis of pH and bacterial sterility test. Simlarly, CAPA for these two failures were not conducted.

08. Moreover, it is pertinent to mention that in addition to above mentioned 03 batches, other 09 batches (cases are in process) were also drawn from FIDs on different occasions and declared as adulterated and substandard. Following are the details:

S. No.	Name of Drug	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Report No. and date	Remarks of CDL & basis of
1	Parapals IV Infusion 100ml (R. No. 088360)	LI-059	02-2020	02-2022	M/s. Inventor Pharma, Karachi.	No.KQ.251/2020 dated 02-10-2020	Substandard -Deep brown colored solution-Does not comply. -pH-Does not comply. -Bacterial sterility-Does not Comply.
2	Parapals IV Infusion 100ml (R. No. 088360)	LI-058	01-2020	01-2022	-do-	No.KQ.250/2020 (Initial) dated 02-10-2020 No.KQ.250/2020 (Final) dated 20-10-2020	Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Complies
3	Parapals IV	LI-115	04-2020	04-2022	-do-	No.KQ.293/2020 dated 07-12-020	Adulterated and Substandard

	Infusion 100ml (R. No. 088360)						-Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Complies
4	Parapals IV Infusion 100ml (R. No. 088360)	LI-129	04-2020	04-2022	-do-	No.KQ.292/2020 dated 07-12-020	Adulterated and Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Does not Comply.
5	Parapals IV Infusion 100ml (R. No. 088360)	LI-237	08-2020	08-2022	-do-	No.KQ.261/2020 dated 03-12-2020	Adulterated and Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply. -Bacterial sterility-Does not Comply.
6	Parapals Infusion	LI-051	01-2020	01-2022	-do-	No.KQ.131/2021 dated 30-06-2021	Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply.
7	Parapals Infusion	LI-052	01-2020	01-2022	-do-	No.KQ.132/2021 dated 30-06-2021	Substandard -Deep brown colored solution-Does not comply. - pH-Does not comply.
8	Parapals Infusion	LI-048	01-2020	01-2022	-do-	No.R.KQ.398/2020 dated 09-12-2020	Adulterated and Substandard -Deep brown colored solution-9Does not comply. - pH-Does not comply.
9	Parapals Infusion	LI-050	01-2020	01-2022	-do-	No.R.KQ.399/2020 dated 09-12-2020	Substandard

							- pH-Does not comply.

Proceedings and Decision of 326th Meeting of Registration Board.

"The Board after considering the facts of the case and after thorough deliberations decided:

i. Suspension of the Registration of Parapals Infusion (Registration No. 088360) under section 42 of the Drugs Act, 1976 and rules framed thereunder, for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by panel with satisfactory report; whichever is later.

ii. Resubmission of RCA and CAPA by the firm regarding all quality attributes of product which are declared non-compliant in CDL reports.

iii. To conduct Product Specific Inspection, including but not limited to following TORs, by panel of inspectors/experts to be nominated by Director QA/LT.

(a) To verify the all aspect of RCA and CAPA submitted by firm in the light of test /analysis report of CDL regarding all quality attributes of product which are declared non-compliant.

(b) To verify manufacturing and compliance of sterile product manufacturing in light of Schedule BI and BII of Drugs(L.R.&A.) rules 1976.

(c) To verify and report manufacturing and testing capacity of SVP/Liquid infusion (Vail) section along with ancillary facilities for contract/toll manufacturing as per in practice format with clear recommendation.

Case No. 11: VOLUNTARY RECALL OF HUMAN ALBUMIN 20% BIOTEST MANUFACTURED BY M/S BIOTEST AG, GMBH

Back Ground:

1. DRAP has received a rapid alert from the Paul-Ehrlich Institute, Federal Institute of Vaccine and Biomedicines, Ministry of Health, Germany, with respect to the quality defect and **voluntary recall** of 06 batches of Human Albumin 20%, 100mL manufactured by the Biotest AG, GmbH. Out of these six batches, one batch was imported in Pakistan by the authorized registration holder M/s Eastren Trade & Distribution Co, (Pvt) Limited, Karachi.

2. In response to this alert QA/LT division issued Medical Product alert dated 07-10-2022 and the importer has been directed to immediately recall the stock of defective batch **C236831P02** from the market. Regulatory field force is directed to supervise the recall progress. Details are:

Product Name	**Reg. No.**	**Lot. No.**	**Mfg. date**	**Exp. date**	**Mfg. by**	**Name of Importer**	**Details of defect/ Reason of Recall**
Human Albumin 20% Biotest	008459	C236821P02	17-09-2021	31-08-2024	M/s. Biotest AG, GmbH	M/s. Eastern Trade & Distribution Co., (Pvt) Limited. Karachi	Suspicious results within determination of endotoxins by monocyte activation test and limulus amoebocyte lysate test 10-11 months after certification for marketing. At the time of batch release rabbit pyrogen test was well within specifications.

3. Accordingly, the importer vide letter dated 28-12-2022 intimated that they had imported 2500 vials of above batch and they have recalled their stock from market and hospitals, after recall they have a stock of 1176 vials in their warehouse and 1324 has been consumed. Accordingly, letter dated 23-01-2023 was issued to Area FID for reconciliation of recalled stock, FID visited their premises on 03-02-2023 and intimated that 1176 vials of above batch are recalled and are present

in their stock. Now firm is requesting for permission to discard/destroy the above said voluntary recalled stock.

4. As per Schedule B-II , section 6.6 and 6.7 mentioned about the storage and destruction recalled stock of recalled product by the manufacturer/importer after intimation to Concerned Board. However, there is no distinction between Regulatory Recall arise after testing and reporting of Governmental testing laboratories and Voluntary Recalls initialed by firms on their own

5. Moreover at page 27 & 29 of DRAP "**,** also mentions about destruction and disposal of recalled stock after intimation to QA/LT division in the presence of FID or panel.

6. Now case is placed before Board for deliberation and consideration regarding fate of recalled Stock arises by Voluntary recall and all such matters of **VOLUNTRY RECALLS,** where in no regulatory action has been initiated due to lack of Test reports form CDL/DTLs.

Proceedings and Decision of 326th Meeting of Registration Board.

"The Board after considering the facts of the case and after thorough deliberations decided that the cases of products which would be recalled in result of any regulatory decision and action with quality attributes would be presented before Board as per requirement of Drug Act 1976 and DRAP Act 2012 and rules frame there under as per ongoing practice.

The Board further decided that in this instant case and related cases wherein the firm has initiated any voluntary recall by itself or on the behalf of their principle abroad wherein no regulatory action is initiated, the case would be processed as per practice in QA/LT division and Director QA/LT shall decide the fate/disposal of the recalled stock in appropriate manner in light of DRAP **Guideline of Rapid Alert and Recall of Defective therapeutic goods".**

Case No. 12: RELAXATION IN LABELING AND PACKING REQUIREMENYTS FOR AMPOULES HAVING CAPACITY OF 2ML OR LESS UNDER DRUGS (LABELLING AND PACKING) RULES 1986.

This is with reference to the request of M/s Friends Glass Pvt Ltd Swabi regarding difficulties in printing of art work on glass ampoules having capacity of 1ml and printing material is so huge that it is not visible with naked eyes and it is more difficult when it comes to printing the same matter on the ampoules.

2. It is submitted that the Rule 3 of The Drugs (Labeling and Packing) Rules, 1986 that deals with labeling requirements is as under: -

(3) Manner of Labeling:

The following particulars shall appear either in print or in writing in indelible ink in a conspicuous manner on a label of the innermost container of drug and also on the in which such container is packed namely: -

(a) The registered name of the drug;

(b) If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;

(c) The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight.

Added by SRC 1122 (i) 86 dated 23-12-1986 Manual of Drug Laws or measures in metric system, or the number of units of activity as the cause may be, expressed: - (i) In the case of oral liquid preparations in terms of contents per specified volume, the volume being indicated in militaries; (ii) In the case of liquid parenteral preparations ready for administration in terms of militaries or percentage by volume or dose. Provided that in the case of a preparation contained in ampoule, it shall be sufficient if the ingredients are shown on the label or wrapper affixed to any package in which such ampoule is issued for sale. (iii) In the case of drugs in solid form intended for parenteral administration in terms of weight or unit per milligram or gram or per container. (iv) In the case of tablets, capsules pill or other units as the case may be; and (v) In the case of other preparations in terms of percentage by weight or volume or unit-age per gram or milliliter as the case may be;

(d) The name and principal place of business of the manufacturer

(e) The drug manufacturing license number.

(f) The drug registration number.

(g) The date of expiry.
(h) Urdu version of the following namely;
(i) Name of drug (ii) dosage; and (iii) Instructions;
(i) The distinctive batch number date of manufacture and the maximum retail price;

Provided that in the case of a drug packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than two milliliter or in an ampoule containing a sterile suture or ligature and such strip foil blister or ampoule is placed in other package and also in the case of printed collapsible tubes it shall be sufficient to give the information on the outer packing containing such strips, foils, blister or ampoule.

Provided further that the registration board may allow relaxation of any of these conditions.

3. It is submitted that drug contained in an ampoule having capacity of not more than 2ml have space constrains to print all the information on the ampoule, furthermore, as per Rule 3 of The Drugs (Labeling and Packing) Rules, 1986 the Registration Board is empowered to allow relaxation of any of labeling and packing conditions.

4. In light of above it is proposed that we may allow the ampoules of capacity of 2ml or less to contain following minimum information: -

i. The registered name of the drug;
ii. If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;
iii. The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight.
iv. The name of the manufacturer
v. The drug manufacturing license number.
vi. The drug registration number.
vii. The date of expiry.
viii. Urdu version of the following namely; (i) Name of drug
ix. The distinctive batch number and the maximum retail price;

Proceedings and Decision of 326th Meeting of Registration Board.

The Board after considering the facts of the case and after thorough deliberations and technical discussion keeping in view of small size of the ampoule which is difficult to print and read, in light of provision of Section 3 of Drugs (Labelling and Packing) Rules 1986 decided following minimum particulars shall appear in print or in writing in indelible ink in a conspicuous manner on the ampoules of capacity of 2ml or less: -

i. Registered name of drug both in Urdu and English version.
ii. International non-proprietary name or Pharmacopoeial name or generic name as the case may be.
iii. DML number.
iv. Registration Number.
v. Expiry Date.
vi. Batch No.
vii. Company Name with District of its Location. (Complete address such as street No., plot etc may be relaxed e. g X (Company), plot No. Y Street Z, ABC Industrial area, Islamabad may be written as **X, Islamabad**)

However, on the outer packing all the information as required under Drugs (Labelling & Packing) Rules 1986 must appear in print or in writing in inedible ink in a conspicuous manner.

Item No. V: Additional Agenda

Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell

Agenda of Mr. Farooq Aslam

Case No. I: Registration applications submitted on Form 5F (Routine Applications):

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2947 dated 31/01/2022
	Details of fee submitted	PKR 30,000/-: dated 18/10/2021
	The proposed proprietary name / brand name	**Dysit 4mg/2ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x5s,1x1s As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	GMP status of the Finished product manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liquid Injection (Ampoule Human General) Section
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ondansetron Hydrochloride USP is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Onset 2mg/ml Injection by M/s Pharmedic (Pvt) Ltd by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin, dist. Suat, Gujarat, INDIA		
API Lot No.	20ON00029 (99.42 anhydrous)		
Description of Pack (Container closure system)	Filled in glass ampoules which are placed in PVC trays and further packed in cardboard unit cartons with 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.	TDX001	TDX002	TDX003
Batch Size	2857 Ampoules	2857 Ampoules	2857 Ampoules
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	13-10-2020	14-10-2020	15-10-2020
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 valid till 01/07/2022 issued by Food and Drugs Control Administration, Gujarat is submitted. Firm has also submitted License issued by Food and Drugs Control Administration, Gujarat valid till 23-01-2026.

III	Documents for the procurement of API with approval from DRAP (in case of import).	Attested Invoice Number: EI/3002100309, Dated 31/08/2020 cleared on 07/10/2020 vide diary number 14289/2020-DRAP.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	**Observations**	**Firm's response**
1	Pharmaceutical equivalence studies have been performed against comparator's product while the studies are required against the innovator's / reference product.	Firm has submitted Pharmaceutical equivalence studies against the Zofran Injection 4mg/2ml (Reg.#084166) of M/s Novartis.
2	Detail of sterilization process for the applied product is not provided. Submit 3protocol for sterilization process along with the relevant information in relevant section.	Firm has submitted details of terminal sterilization to be performed at 121^{o}C for 15 minutes in autoclave.
3	As per USP monograph for performing system suitability testing, the mobile phase containing reference standard (Ondansetron) Ondansetron related compound A should have been prepared while you have prepared the dilution by taking only RS as it is depicted from the submitted chromatograms, clarify.	Firm has submitted that system suitability parameter has been performed as per USP monograph during the analytical method verification studies.
4	Clarification is required regarding the injection volume which is 10uL as per USP while you have selected 20uL for analysis.	The selected injection volume is same for the standard and sample solution and within the range of concentration of linearity.
5	As per submitted documents (BMR), As-is potency is 79.64% while as per COA of drug substance anhydrous potency is 99.42%, justify. Moreover, justify the quantity adjustment that is 15.07gm for 2857 ampoules for 4mg/2mL made as presented in submitted BMR of the applied product along with the complete calculations for potency adjustment.	Firm has submitted detailed calculation for the Assay results for both "on anhydrous basis" and "on as is basis". The potency of 79.64% used for dispensing of drug substance for trial batch manufacturing is justified for adjustment of theoretical factor for the salt form of HCl.
6	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
7	GMP certificate / latest inspection report valid within the last three years	GMP certificate of M/s Wimits Pharmaceuticals issued on basis of inspection conducted on 08-09-2021 has been submitted.

Decision: Approved.

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

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore

4.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan

	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2953 dated 31/01/2022
	Details of fee submitted	PKR 75,000/-: dated 18/10/2021
	The proposed proprietary name / brand name	**Stawia 4mg/2ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x5s,1x1s As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.
	GMP status of the Finished product manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liquid Injection (Ampoule Human General) Section
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ondansetron Hydrochloride USP is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 30°C ± 2°C / 75% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Onset 2mg/ml Injection by M/s Pharmedic (Pvt) Ltd by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin, dist. Suat, Gujarat, INDIA		
API Lot No.	20ON00029		
Description of Pack (Container closure system)	Filled in glass ampoules which are placed in PVC trays and further packed in cardboard unit cartons with 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.	TDX001	TDX002	TDX003
Batch Size	2857 Ampoules	2857 Ampoules	2857 Ampoules
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	13-10-2020	14-10-2020	15-10-2020
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 valid till 01/07/2022 issued by Food and Drugs Control Administration, Gujarat is submitted.
III	Documents for the procurement of API with approval from DRAP (in case of import).	Attested Invoice Number: EI/3002100309, Dated 31/08/2020 cleared on 07/10/2020 vide diary number 14289/2020-DRAP.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:		
1	Form 5F is submitted by the manufacturer which should be from the applicant. Moreover, applicant mentioned in Form 5F is M/s Wimits Pharmaceuticals which is manufacturing site. Submit revised Form 5F signed and stamped by the applicant along with the submission of full fee.	Firm has referred to the submitted covering letter and fee voucher which is from the applicant i.e., M/s Asian Continental and has submitted revised section 1.3.2.
2	Pharmaceutical equivalence studies have been performed against comparator's product while the studies are required against the innovator's / reference product.	Firm has submitted Pharmaceutical equivalence studies against the Zofran Injection 4mg/2ml (Reg.#084166) of M/s Novartis.
3	Detail of sterilization process for the applied product is not provided. Submit protocol for sterilization process along with the relevant information in relevant section.	Firm has submitted details of terminal sterilization to be performed at 121^{o}C for 15 minutes in autoclave.
4	As per USP monograph for performing system suitability testing, the mobile phase containing reference standard (Ondansetron) Ondansetron related compound A should have been prepared while you have prepared the dilution by taking only RS as it is depicted from the submitted chromatograms, clarify.	Firm has submitted that system suitability parameter has been performed as per USP monograph during the analytical method verification studies.
5	Clarification is required regarding the injection volume which is 10uL as per USP while you have selected 20uL for analysis.	The selected injection volume is same for the standard and sample solution and within the range of concentration of linearity.
6	As per submitted documents (BMR), As-is potency is 79.64% while as per COA of drug substance anhydrous potency is 99.42%, justify. Moreover, justify the quantity adjustment (15.07gm for 2857 ampoules for 4mg/2mL and 251.13gm for 8mg/4mL) made as presented in submitted BMR of the applied product along with the complete calculations for potency adjustment.	Firm has submitted detailed calculation for the Assay results for both "on anhydrous basis" and "on as is basis". The potency of 79.64% used for dispensing of drug substance for trial batch manufacturing is justified for adjustment of theoretical factor for the salt form of HCl.
7	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
8	GMP certificate / latest inspection report valid within the last three years	GMP certificate of M/s Wimits Pharmaceuticals issued on basis of inspection conducted on 08-09-2021 has been submitted.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5F 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.**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore

5.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2954 dated 31/01/2022
	Details of fee submitted	PKR 75,000/-: dated 18/10/2021
	The proposed proprietary name / brand name	**Stawia 8mg/4ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ondansetron as Hydrochloride Dihydrate….2mg
	Pharmaceutical form of applied drug	Clear colorless solution for parenteral use (IV/IM) filled in type-I glass ampoules
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x5s,1x1s As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved. 8mg/4mL (PL 04543/0508) 4mg/2mL (PL 04543/0507)
	For generic drugs (me-too status)	Onset 8mg/4ml Injection by M/s Pharmedic (Pvt) Ltd.
	GMP status of the Finished product manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Liquid Injection (Ampoule Human General) Section
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ondansetron Hydrochloride USP is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its

		verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Onset 2mg/ml Injection by M/s Pharmedic (Pvt) Ltd by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin, dist. Suat, Gujarat, INDIA		
API Lot No.	20ON00029 (99.42 anhydrous)		
Description of Pack (Container closure system)	Filled in glass ampoules which are placed in PVC trays and further packed in cardboard unit cartons with 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.	OD001	OD002	OD003
Batch Size	24390 Ampoules	24390 Ampoules	24390 Ampoules
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	13-10-2020	14-10-2020	15-10-2020
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 valid till 01/07/2022 isssued by Food and Drugs Control Administrtaion, Gujarat is submitted.
III	Documents for the procurement of API with approval from DRAP (in case of import).	Attested Invoice Number: EI/3002100309, Dated 31/08/2020 cleared on 07/10/2020 vide diary number 14289/2020-DRAP.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks OF Evaluator:		
1	Form 5F is submitted by the manufacturer which should be from the applicant. Moreover, applicant mentioned in Form 5F is M/s Wimits Pharmaceuticals which is manufacturing site. Submit revised Form 5F signed and stamped by	Firm has referred to the submitted covering letter and fee voucher which is from the applicant i.e., M/s Asian Continental and has submitted revised section 1.3.2.

	the applicant along with the submission of full fee.	
2	Pharmaceutical equivalence studies have been performed against comparator's product while the studies are required against the innovator's / reference product.	Firm has submitted Pharmaceutical equivalence studies against the Zofran Injection 8mg/4ml (Reg.#084165) of M/s Novartis.
3	Detail of sterilization process for the applied product is not provided. Submit protocol for sterilization process along with the relevant information in relevant section.	Firm has submitted details of terminal sterilization to be performed at 121^{o}C for 15 minutes in autoclave.
4	As per USP monograph for performing system suitability testing, the mobile phase containing reference standard (Ondansetron) Ondansetron related compound A should have been prepared while you have prepared the dilution by taking only RS as it is depicted from the submitted chromatograms, clarify.	Firm has submitted that system suitability parameter has been performed as per USP monograph during the analytical method verification studies.
5	Clarification is required regarding the injection volume which is 10uL as per USP while you have selected 20uL for analysis.	The selected injection volume is same for the standard and sample solution and within the range of concentration of linearity.
6	As per submitted documents (BMR), As-is potency is 79.64% while as per COA of drug substance anhydrous potency is 99.42%, justify. Moreover, justify the quantity adjustment (15.07gm for 2857 ampoules for 4mg/2mL and 251.13gm for 8mg/4mL) made as presented in submitted BMR of the applied product along with the complete calculations for potency adjustment.	Firm has submitted detailed calculation for the Assay results for both "on anhydrous basis" and "on as is basis". The potency of 79.64% used for dispensing of drug substance for trial batch manufacturing is justified for adjustment of theoretical factor for the salt form of HCl.
7	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
8	GMP certificate / latest inspection report valid within the last three years	GMP certificate of M/s Wimits Pharmaceuticals issued on basis of inspection conducted on 08-09-2021 has been submitted.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5F 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.**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore

6.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2956 dated 31/01/2022

	Details of fee submitted	PKR 75,000/-: dated 07/01/2022
	The proposed proprietary name / brand name	**Stawia 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……8mg
	Pharmaceutical form of applied drug	Oral solid dosage form
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10's As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 8mg tablet by M/s Pharmedic (Pvt) Ltd.
	GMP status of the Finished product manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ondansetron Hydrochloride USP is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Onset 8mg tablet by M/s Pharmedic by performing quality tests (Identification, Assay, Dissolution, Uniformity of the dosage form). CDP has been performed against the same brand that is Onset 8mg tablet by M/s Pharmedic in Acid media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH

		6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.		
STABILITY STUDY DATA				
Manufacturer of API		M/s CTX Lifesciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin, dist. Suat, Gujarat, INDIA		
API Lot No.		20ON00029 (99.42 anhydrous)		
Description of Pack (Container closure system)		ALu-ALu blister pakced in secondary uit 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.		OE001	OE002	OE003
Batch Size		85000 Tablet	100,000 Tablet	70000 Tablet
Manufacturing Date		04-2021	04-2021	04-2021
Date of Initiation		02-04-2021	07-04-2021	13-04-2021
No. of Batches		03		
Administrative Portion				
I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 valid till 01/07/2022 issued by Food and Drugs Control Administration, Gujarat is submitted.		
III	Documents for the procurement of API with approval from DRAP (in case of import).	Attested Invoice Number: EI/3002100309, Dated 31/08/2020 cleared on 07/10/2020 vide diary number 14289/2020-DRAP.		
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of Evaluator:				
1	Form 5F is submitted by the manufacturer which should be from the applicant. Moreover, applicant mentioned in Form 5F is M/s Wimits Pharmaceuticals which is manufacturing site. Submit revised Form 5F signed and stamped by the applicant along with the submission of full fee.	Firm has referred to the submitted covering letter and fee voucher which is from the applicant i.e., M/s Asian Continental and has submitted revised section 1.3.2.		
2	Pharmaceutical equivalence studies have been performed against comparator's product while the studies are required against the innovator's / reference product.	Firm has submitted Pharmaceutical equivalence studies against the Zofran 8mg tablet (Reg.#084164) of M/s Novartis along with CDP studies in three dissolution		

		mediums of pH 1.2,4.5 & 6.8 with acceptable results of f2 value
3	As per USP monograph of the applied product, the strength of the standard solution is 0.05mg/mL while as per submitted method of analysis the strength of 0.01mg/mL, clarity.	Firm has submitted that it was a typographic error whereas the actual performance has been with the concentration of 0.05mg/ml as evident from the submitted raw data sheets for stability studies.
4	As per USP monograph for performing system suitability testing for drug substance, the mobile phase containing reference standard (Ondansetron) Ondansetron related compound A should have been prepared while you have prepared the dilution by taking only RS as it is depicted from the submitted chromatograms, clarify.	Firm has submitted that system suitability parameter has been performed as per USP monograph during the analytical method verification studies.
5	As per labelling requirement described in official USP monograph of the applied product, when more than one Dissolution test is given, the labeling states the Dissolution test used only if Test 1 is not used. Test 3 is selected for dissolution test for the product but the label of the product does not contain any such information. Submit revised labelling indicating that the product complies with USP Dissolution Test 03.	Firm has submitted revised labelling specimen with declaration of USP Dissolution test 3.
6	As per submitted documents (BMR), As-is potency is 79.64% while as per COA of drug substance anhydrous potency is 99.42%, justify. Moreover, justify the quantity adjustment (0.85kg for 8mg tablet) made as presented in submitted BMR of the applied product along with the complete calculations for potency adjustment.	Firm has submitted detailed calculation for the Assay results for both "on anhydrous basis" and "on as is basis". The potency of 79.64% used for dispensing of drug substance for trial batch manufacturing is justified for adjustment of theoretical factor for the salt form of HCl.
7	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
8	GMP certificate / latest inspection report valid within the last three years	GMP certificate of M/s Wimits Pharmaceuticals issued on basis of inspection conducted on 08-09-2021 has been submitted.
9	Compatibility studies of excipients with the drug substance are required since excipients used in the applied formulation are different from the excipients used by the innovator.	Firm has submitted drug excipient compatibility studies for the binary combination of drug substance with each excipient.
Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5F 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.** **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore**		
7.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2955 dated 31/01/2022
	Details of fee submitted	PKR 75,000/-: dated 07/01/2022
	The proposed proprietary name / brand name	**Stawia 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate……4mg
	Pharmaceutical form of applied drug	Oral solid dosage form
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x10s As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (4mg and 8mg film coated tablet).
	For generic drugs (me-too status)	Onset 4mg tablet by M/s Pharmedic (Pvt) Ltd.
	GMP status of the Finished product manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Tablet (General Human) section
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ondansetron Hydrochloride USP is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Onset 4mg tablet by M/s Pharmedic by performing quality tests (Identification, Assay, Dissolution, Uniformity of the dosage form). CDP has been performed against the same brand that is Onset 4mg tablet by M/s Pharmedic in Acid media (pH-1.2), Acetate Buffer (pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin, dist. Suat, Gujarat, INDIA		
API Lot No.	20ON00029 (99.42 anhydrous)		
Description of Pack (Container closure system)	ALu-ALu blister pakced in secondary uit 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.	TOB001	TOB002	TOB003
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	20-04-2021	26-04-2021	30-04-2021
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 valid till 01/07/2022 issued by Food and Drugs Control Administration, Gujarat is submitted.
III	Documents for the procurement of API with approval from DRAP (in case of import).	Attested Invoice Number: EI/3002100309, Dated 31/08/2020 cleared on 07/10/2020 vide diary number 14289/2020-DRAP.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

1	Form 5F is submitted by the manufacturer which should be from the applicant. Moreover, applicant mentioned in Form 5F is M/s Wimits Pharmaceuticals which is manufacturing site. Submit revised Form 5F signed and stamped by the applicant along with the submission of full fee.	Firm has referred to the submitted covering letter and fee voucher which is from the applicant i.e., M/s Asian Continental and has submitted revised section 1.3.2.
2	Pharmaceutical equivalence studies have been performed against comparator's product while the studies are required against the innovator's / reference product.	Firm has submitted Pharmaceutical equivalence studies against the Zofran 8mg tablet (Reg.#084163) of M/s Novartis along with CDP studies in three dissolution mediums of pH 1.2,4.5 & 6.8 with acceptable results of f2 value
3	As per USP monograph of the applied product, the strength of the standard solution is 0.05mg/mL while as per submitted method of analysis the strength of 0.01mg/mL, clarity.	Firm has submitted that it was a typographic error whereas the actual performance has been with the concentration of 0.05mg/ml as evident from the submitted raw data sheets for stability studies.
4	As per USP monograph for performing system suitability testing for drug substance, the mobile phase containing reference standard (Ondansetron) Ondansetron related compound A should have been prepared while you have prepared the dilution by taking only RS as it is depicted from the submitted chromatograms, clarify.	Firm has submitted that system suitability parameter has been performed as per USP monograph during the analytical method verification studies.
5	As per labelling requirement described in official USP monograph of the applied product, when more than one Dissolution test is given, the labeling states the Dissolution test used only if Test 1 is not used. Test 3 is selected for dissolution test for the product but the label of the product does not contain any such information. Submit revised labelling indicating that the product complies with USP Dissolution Test 03.	Firm has submitted revised labelling specimen with declaration of USP Dissolution test 3.
6	As per submitted documents (BMR), As-is potency is 79.64% while as per COA of drug substance anhydrous potency is 99.42%, justify. Moreover, justify the quantity adjustment (0.85kg for 8mg tablet) made as presented in submitted BMR of the applied product along with the complete calculations for potency adjustment.	Firm has submitted detailed calculation for the Assay results for both "on anhydrous basis" and "on as is basis". The potency of 79.64% used for dispensing of drug substance for trial batch manufacturing is justified for adjustment of theoretical factor for the salt form of HCl.
7	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
8	GMP certificate / latest inspection report valid within the last three years	GMP certificate of M/s Wimits Pharmaceuticals issued on basis of inspection conducted on 08-09-2021 has been submitted.
9	Compatibility studies of excipients with the drug substance are required since excipients used in the applied formulation are different from the excipients used by the innovator.	Firm has submitted drug excipient compatibility studies for the binary combination of drug substance with each excipient.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5F 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.**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore		
8.	Name, address of Applicant / Marketing Authorization Holder	M/s Asian Continentals House, D-133, Tipu Sultan Road, KDA Scheme 1, Karachi-Pakistan
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2952 dated 31/01/2022
	Details of fee submitted	PKR 75,000/-: dated 07/01/2022
	The proposed proprietary name / brand name	**Stawia 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Ondansetron as Hydrochloride Dihydrate.....4mg
	Pharmaceutical form of applied drug	Almost colorless, clear oral liquid with characteristic odour of strawberry.
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	1x50ml As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (4mg/5mL)
	For generic drugs (me-too status)	Onset 4mg/5ml Syrup by M/s Pharmedic (Pvt) Ltd. Registration number:025996
	GMP status of the Finished product manufacturer	M/s Wimits Pharmaceuticals: GMP certificate No. 70/2021 DRAP (FID / 2061717-540) Dated: 08/09/2021 Syrup (General Human) Section
	Name and address of API manufacturer.	M/s CTX Lifesciences Pvt. Ltd. Address:Block No. 251-252 Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230,Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ondansetron Hydrochloride USP is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ON130001, ON130002, ON130003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Onset 4mg/5ml Syrup by M/s Pharmedic (Pvt) Ltd by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification/validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s CTX Lifesciences Pvt. Ltd. Address: Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 278/P, 279 to 282, 283/P, 284/P, GIDC, Sachin, dist. Suat, Gujarat, INDIA		
API Lot No.	20ON00029 (99.42 anhydrous)		
Description of Pack (Container closure system)	Amber colred 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.	ON001	ON002	ON003
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	04-05-2021	05-05-2021	06-05-2021
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19061470 valid till 01/07/2022 isssued by Food and Drugs Control Administrtaion, Gujarat is submitted.
III	Documents for the procurement of API with approval from DRAP (in case of import).	Attested Invoice Number: EI/3002100309, Dated 31/08/2020 cleared on 07/10/2020 vide diary number 14289/2020-DRAP.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks OF Evaluator:		
1	Form 5F is submitted by the manufacturer which should be from the applicant. Moreover, applicant mentioned in Form 5F is M/s Wimits Pharmaceuticals which is manufacturing site. Submit revised Form 5F signed and stamped by the applicant along with the submission of full fee.	Firm has referred to the submitted covering letter and fee voucher which is from the applicant i.e., M/s Asian Continental and has submitted revised section 1.3.2.
2	Pharmaceutical equivalence studies have been performed against comparator's product while the studies are required against the innovator's / reference product.	Firm has submitted that Innovator product i.e., Zofran is not registered din Pakistan.
4	As per USP monograph for performing system suitability testing for drug substance, the mobile phase containing reference standard (Ondansetron) Ondansetron related compound A should have been prepared while you have prepared the dilution by taking only RS as it is depicted from the submitted chromatograms, clarify.	Firm has submitted that system suitability parameter has been performed as per USP monograph during the analytical method verification studies.
5	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6	GMP certificate / latest inspection report valid within the last three years	GMP certificate of M/s Wimits Pharmaceuticals issued on basis of inspection conducted on 08-09-2021 has been submitted.
7	Compatibility studies of excipients with the drug substance are required since excipients used in the applied formulation are different from the excipients used by the innovator.	Firm has submitted drug excipient compatibility studies for the binary combination of drug substance with each excipient.
8	As per submitted documents (BMR), As-is potency is 79.64% while as per COA of drug substance anhydrous potency is 99.42%, justify. Moreover, justify the quantity adjustment (301.3gm for the applied product) made as presented in submitted BMR of the applied product along with the complete calculations for potency adjustment.	Firm has submitted detailed calculation for the Assay results for both "on anhydrous basis" and "on as is basis". The potency of 79.64% used for dispensing of drug substance for trial batch manufacturing is justified for adjustment of theoretical factor for the salt form of HCl.

Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5F 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.**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate Raiwind Road, Lahore

9.	Name, address of Applicant / Marketing Authorization Holder	M/s Stallion Pharmaceuticals (Pvt.) Ltd, plot # 581 Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, 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. 2374 dated 25/01/2022.
	Details of fee submitted	Rs. 75,000/-: dated 28/12/2021.
	The proposed proprietary name / brand name	**Warner 100 mg tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lacosamide…….100 mg
	Pharmaceutical form of applied drug	immediate release Film coated tablet.
	Pharmacotherapeutic Group of (API)	Other Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	1x 14's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Vimpat Tablet (50mg, 100mg, 150mg, 200mg) USFDA Approved by M/s Schwarz Biosciences, Inc.
	For generic drugs (me-too status)	Lalap 100 mg Tablet by M/s Genix Pharma Private Limited.
	GMP status of the Finished product manufacturer	Stallion: Copy of GMP certificate No. 131/2020-DRAP(AD-1952624-1099) dated 02-10-2020 issued on the basis of inspection conducted on 22-09-2020. Bio-Mark: Copy of GMP certificate No. 47/2020-DRAP(AD-849966-789 dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020. Tablet General Section
	Name and address of API manufacturer.	M/s Venkata Narayana Active Ingredients Private Limited., Sy. N. 69, Chandrapadiya (V), Vinjamur (Mandal), SPSR Nellore District 524228, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Lacosamide is present in BP/EP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (20BLac/05-15/022, Lac/05-15/023, Lac/05-15/021)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator's product that is Vimpat 100mg tablet by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form) (Batch number VMP510). CDP has been performed against the same brand 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 Venkata Narayana Active Ingredients Private Limited.		
API Lot No.	LC0030120.		
Description of Pack (Container closure system)	Alu Alu. Blisters with aluminum foil having leaflet and packed in unit carton of bleach board.		
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.	20B222	20K335	21C261
Batch Size	140,000	70,000	70,000
Manufacturing Date	10/2020	10/2020	10/2020
Date of Initiation	10/10/2020	15/10/2020	20/10/2020
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2970/MIA/Mfg/2018 issued by Drugs Control Administration, Andhra Pradesh valid till 13/09/2021.
III	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice with invoice # DXP192030396 Dated 17/03/2020 is submitted wherein the permission to import different APIs including Lacosamide for the purpose of test/analysis and stability studies is granted.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
Remarks of Evaluator-I:		
1	The address of drug substance manufacturer mentioned in GMP certificate is different from the address mentioned in Form 5F, clarify.	Firm has declared it as typo error and submitted that Details of Drug substance manufacturer are same as presented in section 3.2.S.2.1, GMP certificate and COA of drug substance.
2	Provide complete batch manufacturing record for the applied product.	Submitted
3	Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
4	Provide detail of strength of serial dilutions prepared for accuracy testing in analytical method verifications studies for drug product.	Frim has submitted details of concentrations as 0.5mg/ml, 1mg/ml & 1.5mg/ml against the concentration levels of 50%, 100%, & 150% respectively.
5	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted
6	Provide Documents (invoice) for the procurement of API with approval from DRAP (in case of import.	Commercial invoice attested by AD DRAP I&E Lahore Dated 21-04-2020 is submitted

Decision: Approved.

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

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sundar Industrial Estate Lahore.

10.	Name, address of Applicant / Marketing Authorization Holder	M/s Stallion Pharmaceuticals (Pvt.) Ltd, plot # 581 Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, 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. 2373 dated 25/01/2022.
	Details of fee submitted	Rs. 75,000/-: dated 28/12/2021.
	The proposed proprietary name / brand name	**Warner 50 mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lacosamide…….50 mg
	Pharmaceutical form of applied drug	immediate release Film coated tablet.
	Pharmacotherapeutic Group of (API)	Other Anti-epileptics
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	1x 14's
	Proposed unit price	As per SRO.

	The status in reference regulatory authorities	Vimpat Tablet (50mg, 100mg, 150mg, 200mg) USFDA Approved by M/s Schwarz Biosciences, Inc.
	For generic drugs (me-too status)	Lalap 50 mg Tablet by M/s Genix Pharma Private Limited; Registration # 070470.
	GMP status of the Finished product manufacturer	Stallion: Copy of GMP certificate No. 131/2020-DRAP(AD-1952624-1099) dated 02-10-2020 issued on the basis of inspection conducted on 22-09-2020. Bio-Mark: Copy of GMP certificate No. 47/2020-DRAP(AD-849966-789 dated 26-02-2020 issued on the basisi of inspection conducted on 13-02-2020.
	Name and address of API manufacturer.	M/s Venkata Narayana Active Ingredients Private Limited., Sy. N. 69, Chandrapadiya (V), Vinjamur (Mandal), SPSR Nellore District 524228, Andhra Pradesh, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Lacosamide is present in BP/EP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	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: (20BLac/05-15/022, Lac/05-15/023, Lac/05-15/021)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator's product that is Vimpat 50mg tablet by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form) (Batch number VMP205). CDP has been performed against the same brand 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 Venkata Narayana Active Ingredients Private Limited.		
API Lot No.	LC0030120.		
Description of Pack (Container closure system)	Alu Alu. Blisters with aluminum foil having leaflet and packed in unit carton of bleach board.		
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.	20B217	20E259	20G282
Batch Size	70,000	150,000	70,000
Manufacturing Date	04/2020	04/2020	04/2020
Date of Initiation	17/04/2020	20/04/2020	22/04/2020
No. of Batches	03		

Administrative Portion		
I	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2970/MIA/Mfg/2018 issued by Drugs Control Administration, Andhra Pradesh valid till 13/09/2021.
III	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice with invoice # DXP192030396 Dated 17/03/2020 is submitted wherein the permission to import different APIs including Lacosamide for the purpose of test/analysis and stability studies is granted.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
Remarks OF Evaluator-I:		
1	The address of drug substance manufacturer mentioned in GMP certificate is different from the address mentioned in Form 5F, clarify.	Firm has declared it as typo error and submitted that Details of Drug substance manufacturer are same as presented in section 3.2.S.2.1, GMP certificate and COA of drug substance.
2	Provide complete batch manufacturing record for the applied product.	Submitted
3	Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
4	Provide detail of strength of serial dilutions prepared for accuracy testing in analytical method verifications studies for drug product.	Frim has submitted details of concentrations as 0.5mg/ml, 1mg/ml & 1.5mg/ml against the concentration levels of 50%, 100%, & 150% respectively.
5	Proivde Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

6	Provide Documents (invoice) for the procurement of API with approval from DRAP (in case of import.	Commercial invoice attested by AD DRAP I&E Lahore Dated 21-04-2020 is submitted

Decision: Approved.

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

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sundar Industrial Estate Lahore.

11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 18-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 27-06-2019, declaring grant following additional sections: "Capsule (Cephalosporin) Dry powder suspension (Cephalosporin) Dry Powder injection (Cephalosporin)"
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 11280 dated 13-04-2021
	Details of fee submitted	Rs.20,000/- dated 05-01-2021
	The proposed proprietary name / brand name	**M-Xime 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cefixime as Trihydrate…400mg
	Pharmaceutical form of applied drug	Capsuel
	Pharmacotherapeutic Group of (API)	Third-Generation Cephalosporin's
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Cefspan capsule
	Name and address of API manufacturer.	M/s Pharmagen Ltd., Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies & CDP studies against the reference product of "Cefspan capsule of M/s Barret Hodgson Karachi" has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA

Manufacturer of APIs	M/s Pharmagen Ltd., Ferozpur Road, Lahore		
API Lot No.	004243/022/2020		
Description of Pack (Container closure system)	Alu Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20DST04	20DST05	20DST06
Batch Size	5000 capsule	5000 capsule	5000 capsule
Manufacturing Date	02-2020	02-2020	02-2020

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued on basis of inspection conducted on 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice for 10Kg of Cefixime has been submitted.
4.	Data of stability batches will be supported by attested respective	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.

	documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)
Remarks of Evaluator: Firm had initially applied USP specifications instead of the monograph notified by DRAP in its 313th meeting. Upon communication of observation firm has submitted revised stability studies data of three batches for both accelerated and long-term stability studies as per the monograph of Cefixime capsule notified by DRAP.		
Decision: Approved with manufacturer specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in stability data 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.**		

Agenda of Evaluator PEC-II

Case No. 01 Registration applications of Export facilitation cases

a. New Cases

12.	Name and address of manufacturer / Applicant	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	**T-Penta Tablets 75mg**
	Composition	Each film-coated tablet contains: Tapentadol HCl equivalent to Tapentadol....75mg
	Diary No. Date of R& I & fee	Dy. No. dated 05-10-2014 Fee Rs: 50,000/- dated 22.09.2014 vide deposit slip No.0142841. Fee Rs: 25,000/- dated 23.02.2023 vide deposit slip No.3403466086.
	Pharmacological Group	Other Opioids Analgesics (ATC Code: N02AX06)
	Type of Form	Form 5D
	Finished product Specifications	Manufcaturer's Specs.
	Pack size & Demanded Price	10's ; Rs. 750/-
	Approval status of product in Reference Regulator Authorities	Nucynta Tablets 75mg by M/s Janssen Pharms - USA. (US-FDA Approved)
	Me-too status	Tapento Tablets 75mg by M/s Sami Pharmaceutical (Pvt.) Ltd., Karachi. (Reg. No. 093064)
	GMP status	Last GMP Inspection dated 17-01-2023 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an acceptable level of compliance of GMP requirements. Tablet section approved.
	Remarks of the Evaluator	
STABILITY STUDY DATA		
Manufacturer of API	M/s RA Chem Pharma Ltd, R.S.No. 50/1, Mukteswarapuram (V), Jaggaiahpet (M), Krishna Dist-521175, Andhra Pradesh, India.	

API Lot No.	TPL/505/03/20		
Description of Pack (Container closure system)	Alu-PVDC blister packed in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	**563DS01**	**563DS02**	**563DS03**
Batch Size	2,000 tablets	2,000 tablets	2,000 tablets
Manufacturing Date	24-11-2020	24-11-2020	24-11-2020
Date of Initiation	02-12-2020	02-12-2020	02-12-2020
No. of Batches	03		
Date of Submission	26-10-2021		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
57.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product for Estine (Ebastine) Tablets 10mg & 20mg on 6th May, 2019. Further, the said panel inspection report was discussed in 289th Drug Registration Board meeting held on 14th – 16th May 2019. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
58.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs **(Batch# TPL/505/03/20)** of API from **M/s RA Chem Pharma Ltd.**, R.S. No. 50/1, Mukteswarapuram (V), Jaggaiahpet (M), Krishna Dist-521175, Andhra Pradesh, India. and M/s Getz Pharma (Pvt.) Limited Karachi are submitted.
59.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of API from both API Manufacturer and Finished Product Manufacturer are provided by the firm.
60.	Stability study data of API from API manufacturer	Firm has submitted stability study data of API as per zone IVA. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 06 months at intervals 0, 3, 6, 9, 12, 24 & 0, 1, 2, 3 & 6 months respectively. Batches: TPL/03/502/19, TPL/03/503/19, TPL/03/504/19)
61.	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 RA Chem Pharma Ltd.,** R.S. No. 50/1, Mukteswarapuram (V), Jaggaiahpet (M), Krishna Dist-521175, Andhra Pradesh, India issued, dated 19-07-2019 by Directorate of Drug Control Administration, Government of Andhra Pradesh valid till 19-07-2022.

<table>
<tr><td>62.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>TPL/505/03/20</td><td>RAAP/20-21/820</td><td>1.0 Kg</td><td>09-11-2020</td></tr></table></td></tr>
<tr><td>63.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>64.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>65.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has submitted a commitment that same excipients have been used as used by innovator ‘Nucynta Tablets 75mg’. However, there is only difference in film coating materials Therefore, Drug-excipients compatibility studies were not performed.</td></tr>
<tr><td>66.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>563DS01</td><td>2,000 tablets</td><td>24-11-2020</td></tr><tr><td>563DS02</td><td>2,000 tablets</td><td>24-11-2020</td></tr><tr><td>563DS03</td><td>2,000 tablets</td><td>24-11-2020</td></tr></table></td></tr>
<tr><td>67.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative Dissolution Profile of T-Penta Tablets 75mg Batch No. 563DS01 was performed against Comparator Product Tapento IR Tablets 75mg Batch No. 001G in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.</td></tr>
<tr><td>68.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>69.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>70.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
</table>

Remarks of Evaluator:

Sr.#	Observations	Firm’s response
1.	Submit valid GMP certificate issued by the relevant regulatory authority for the drug substance manufacturer.	This is to bring to your kind attention that due to business decision following changes /amendments has been made in name of drug manufacturer of Tapentadol HCI which has been effected from 01.11.2022. However, there is no change in manufacturing site address. In context of above firm has submitted valid GMP certificate with the name of Cohance Lifesciences Limited (valid till 13-12-2023), issued by Drug Control Administration Andhra Pradesh, India
2.	• Details shall be submitted for the dissolution parameters adopted	• Firm has submitted details of dissolution parameters for the CDP studies.

		for the performance of CDP studies. • Justification shall be submitted for not performing CDP studies against the innovator drug product.	• With reference to DRAP GUIDANCE DOCUMENT FOR for not performing CDP studies SUBMISSION OF APPLICATION ON FORM 5-F (CTD) FOR against the innovator drug REGISTRATION OF PHARMACEUTICAL DRUG PRODUCTS FOR product. HUMAN USE wherein it is mentioned as "The comparison of the developed formulation and the innovator /reference / comparator product including the" results of all the quality tests shall be submitted and discussed". In light of above provision, we have performed CDP studies of T-Penta Tablets 75mg against Comparator Product that is Tapento IR Tablets 75mg manufactured by M/s Sarni Pharmaceutical (Pvt.) Ltd., Karachi.
	3.	Justification shall be submitted for the dissolution parameters and limits for the drug product batch release.	We have adopted dissolution parameter and limit for T-Penta Tablets 75mg from "Clinical Pharmacology and Biopharmaceutics Review(s)" document of innovator product NUCYNTA Tablets 75mg.

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.

- **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.**

13.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1055 dated 12-01-2023
	Details of fee submitted	Rs.75,000/- dated 04-01-2023
	The proposed proprietary name / brand name	**EMTRO XR 12.5/2.5/1000mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	EMTRO XR 12.5/2.5/1000mg Tablets Each Film coated tablet contains: Empagliflozin……...12.5mg Linagliptin……2.5mg Metformin HCl……1000mg (as Extended-Release)
	Pharmaceutical form of applied drug	Pink color, biconvex, oblong shaped, film coated tablets, plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications

	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by USFDA and marketed in US, with the name of TRIJARDY XR Tablets
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New GMP granted on 05/08/2022 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155 **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular mass, general properties, appearance, solubilities, chirality, partition coefficient, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		Linagliptin: Official monograph of Linagliptin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular formula, general properties, solubilities, physical form, melting range, pka value, hygroscopicity, chirality, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin HCl:** Official monograph of Metformin HCl is present in USP. The firm has submitted details of nomenclature, structure, molecular mass, relative molecular mass, general properties, solubilities, physical form, melting temperature, pH, pKa, chirality, polymorphism, Organoleptic properties, hygroscopicity, partition coefficient, ultraviolet absorption maxima, molar absorptivity, loss on drying, log P, stereochemistry, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**EMPAGLIFLOZIN:** Stability study conditions: Long-term (I): 25°C ± 2ºC & RH 60%+/- 5% for 12 months Long-term (II): 30°C ± 2ºC & RH 65%+/- 5% for 12 months Accelerated: 40°C ± 2ºC & RH 75%+/- 5% for 6 months Batches: [H-E-20210605-D01-E06-01, H-E-20210605-D01-E06-02, L-E-20210414-D01-E06-01] **LINAGLIPTIN:** Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [LGLT-201405001, LGLT-201405002, LGLT-201405003] **METFORMIN HYDROCHLORIDE:** Stability study conditions: Long term: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [MEF/1510145, MEF/1510146, MEF/1510147]
	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 Trijardy XR 12.5mg + 2.5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 12.5mg + 2.5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness, and system suitability

STABILITY STUDY DATA

Manufacturer of API	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155		
API Lot No.	**EMPAGLIFLOZIN:** H-E-20210605-D01-E06-01 **LINAGLIPTIN:** LGLT-RD202011202 **METFORMIN HCl:** MEF/11072155		
Description of Pack (Container closure system)	ALU-ALU Blister in Unit Carton		
Stability Storage Condition	Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21PD-252	21PD-253	21PD-254
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Jan-2022	Jan-2022	Jan-2022
Date of Initiation	Jan-2022	Jan-2022	Jan-2022
No. of Batches	03		

14.	**Name, address of Applicant / Marketing Authorization Holder**	**The Searle Company Limited** **F-319, S.I.T.E., Karachi, Pakistan.**
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1057 dated 12-01-2023
	Details of fee submitted	Rs.75,000/- dated 03-01-2023
	The proposed proprietary name / brand name	**EMTRO XR 25/5/1000mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	EMTRO XR 25/5/1000mg Tablets Each Film coated tablet contains: Empagliflozin……...25mg Linagliptin……5mg Metformin HCl……1000mg (as Extended-Release)
	Pharmaceutical form of applied drug	Yellow color, biconvex, oblong shaped, film coated tablets, plain from both sides.
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by USFDA and marketed in US, with the name of TRIJARDY XR Tablets
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New GMP granted on 05/08/2022 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155 **Approval of Manufacturing Facility:** GMP

		Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular mass, general properties, appearance, solubilities, chirality, partition coefficient, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Linagliptin:** Official monograph of Linagliptin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular formula, general properties, solubilities, physical form, melting range, pka value, hygroscopicity, chirality, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin HCl:** Official monograph of Metformin HCl is present in USP. The firm has submitted details of nomenclature, structure, molecular mass, relative molecular mass, general properties, solubilities, physical form, melting temperature, pH, pKa, chirality, polymorphism, Organoleptic properties, hygroscopicity, partition coefficient, ultraviolet absorption maxima, molar absorptivity, loss on drying, log P, stereochemistry, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**EMPAGLIFLOZIN:** Stability study conditions: Long-term (I): 25°C ± 2ºC & RH 60%+/- 5% for 12 months Long-term (II): 30°C ± 2ºC & RH 65%+/- 5% for 12 months Accelerated: 40°C ± 2ºC & RH 75%+/- 5% for 6

		months Batches: [H-E-20210605-D01-E06-01, H-E-20210605-D01-E06-02, L-E-20210414-D01-E06-01] **LINAGLIPTIN:** Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [LGLT-201405001, LGLT-201405002, LGLT-201405003] **METFORMIN HYDROCHLORIDE:** Stability study conditions: Long term: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [MEF/1510145, MEF/1510146, MEF/1510147]
	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 Trijardy XR 25mg + 5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 25mg + 5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness, and system suitability

STABILITY STUDY DATA	
Manufacturer of API	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155
API Lot No.	**EMPAGLIFLOZIN:**

		H-E-20210605-D01-E06-01 **LINAGLIPTIN:** LGLT-RD202011202 **METFORMIN HCl:** MEF/11072155		
Description of Pack (Container closure system)		ALU-ALU Blister in Unit Carton		
Stability Storage Condition		Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)		
Batch No.		21PD-255	21PD-256	21PD-257
Batch Size		2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date		Jan-2022	Jan-2022	Jan-2022
Date of Initiation		Jan-2022	Jan-2022	Jan-2022
No. of Batches		03		
15.	**Name, address of Applicant / Marketing Authorization Holder**	**The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.**		
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales		
	Dy. No. and date of submission	Dy.No 1056 dated 12-01-2023		
	Details of fee submitted	Rs.75,000/- dated 04-01-2023		
	The proposed proprietary name / brand name	**EMTRO XR 10/5/1000mg Tablets**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	EMTRO XR 10/5/1000mg Tablets Each Film coated tablet contains: Empagliflozin……...10mg Linagliptin……5mg Metformin HCl……1000mg (as Extended-Release)		
	Pharmaceutical form of applied drug	Light yellow color, biconvex, oblong shaped, film coated tablets, plain from both sides		
	Pharmacotherapeutic Group of (API)	Anti-diabetic		
	Reference to Finished product specifications	Innovator's Specifications		
	Proposed Pack size	As per DPC		
	Proposed unit price	As per DPC		
	The status in reference regulatory authorities	Approved by USFDA and marketed in US, with the name of TRIJARDY XR Tablets		
	For generic drugs (me-too status)	N/A		
	GMP status of the Finished product manufacturer	New GMP granted on 05/08/2022 Tablet (General & General Antibiotic) section approved.		

	Name and address of API manufacturer.	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155 **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular mass, general properties, appearance, solubilities, chirality, partition coefficient, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Linagliptin:** Official monograph of Linagliptin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular formula, general properties, solubilities, physical form, melting range, pka value, hygroscopicity, chirality, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin HCl:** Official monograph of Metformin HCl is present in USP. The firm has submitted details of nomenclature, structure, molecular mass, relative molecular mass, general properties, solubilities, physical form, melting temperature, pH, pKa, chirality, polymorphism, Organoleptic properties, hygroscopicity, partition coefficient, ultraviolet absorption maxima, molar absorptivity, loss on drying, log P, stereochemistry, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**EMPAGLIFLOZIN:** Stability study conditions: Long-term (I): 25°C ± 2ºC & RH 60%+/- 5% for 12 months Long-term (II): 30°C ± 2ºC & RH 65%+/- 5% for 12 months Accelerated: 40°C ± 2ºC & RH 75%+/- 5% for 6 months Batches: [H-E-20210605-D01-E06-01, H-E-20210605-D01-E06-02, L-E-20210414-D01-E06-01] **LINAGLIPTIN:** Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [LGLT-201405001, LGLT-201405002, LGLT-201405003] **METFORMIN HYDROCHLORIDE:** Stability study conditions: Long term: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [MEF/1510145, MEF/1510146, MEF/1510147]
	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 Trijardy XR 10mg + 5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).

		CDP has been performed against the same brand that is Trijardy XR 10mg + 5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness, and system suitability

STABILITY STUDY DATA

Manufacturer of API	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155		
API Lot No.	**EMPAGLIFLOZIN:** H-E-20210605-D01-E06-01 **LINAGLIPTIN:** LGLT-RD202011202 **METFORMIN HCl:** MEF/11072155		
Description of Pack (Container closure system)	ALU-ALU Blister in Unit Carton		
Stability Storage Condition	Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	21PD-249	21PD-250	21PD-251
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Dec-2021	Dec-2021	Dec-2021
Date of Initiation	Jan-2022	Jan-2022	Jan-2022
No. of Batches	03		

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

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 1054 dated 12-01-2023
	Details of fee submitted	Rs.75,000/- dated 04-01-2023
	The proposed proprietary name / brand name	**EMTRO XR 5/2.5/1000mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	EMTRO XR 5/2.5/1000mg Tablets Each Film coated tablet contains: Empagliflozin……...5mg Linagliptin…….2.5mg Metformin HCl……1000mg (as Extended-Release)
	Pharmaceutical form of applied drug	Pink color, biconvex, oblong shaped, film coated tablets, plain from both sides.
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by USFDA and marketed in US, with the name of TRIJARDY XR Tablets
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New GMP granted on 05/08/2022 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155 **Approval of Manufacturing Facility:** GMP Attached. **Vendor Qualification:** Documents Based **Reason:** Due to GMP Certificate
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular mass, general properties, appearance, solubilities, chirality, partition coefficient, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Linagliptin:** Official monograph of Linagliptin is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, molecular formula, relative molecular formula, general properties, solubilities, physical form, melting range, pka value, hygroscopicity, chirality, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin HCl:** Official monograph of Metformin HCl is present in USP. The firm has submitted details of nomenclature, structure, molecular mass, relative molecular mass, general properties, solubilities, physical form, melting temperature, pH, pKa, chirality, polymorphism, Organoleptic properties, hygroscopicity, partition coefficient, ultraviolet absorption maxima, molar absorptivity, loss on drying, log P, stereochemistry, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**EMPAGLIFLOZIN:** Stability study conditions: Long-term: 30°C ± 2ºC & RH 65%+/- 5% for 12 months Accelerated: 40°C ± 2ºC & RH 75%+/- 5% for 6 months **LINAGLIPTIN:** Stability study conditions: Long term: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: [LGLT-201405001, LGLT-201405002, LGLT-201405003] **METFORMIN HYDROCHLORIDE:**

		Stability study conditions: Long term: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: [MEF/1510145, MEF/1510146, MEF/1510147]
	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 Trijardy XR 5mg + 2.5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Trijardy XR 5mg + 2.5mg + 1000mg tablet, USFDA (US) approved by BOEHRINGER INGELHEIM PHARMACEUTICALS INC in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness, and system suitability

STABILITY STUDY DATA	
Manufacturer of API	**EMPAGLIFLOZIN:** **Manufacturer:** Fuxin Long Rui Pharmaceutical Co., Ltd **Address:** Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **LINAGLIPTIN:** **Manufacturer:** Ruyuan Hec Pharm Co., Ltd **Address:** Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R.China **METFORMIN HCl:** **Manufacturer:** Aarti Drugs Limited **Address:** Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat . India.396155
API Lot No.	**EMPAGLIFLOZIN:** H-E-20210605-D01-E06-01 **LINAGLIPTIN:** LGLT-RD202011202 **METFORMIN HCl:** MEF/11072155
Description of Pack (Container closure system)	ALU-ALU Blister in Unit Carton
Stability Storage Condition	Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)

Batch No.		21PD-246	21PD-247	21PD-248
Batch Size		2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date		Jan-2022	Jan-2022	Jan-2022
Date of Initiation		Feb-2022	Feb-2022	Feb-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 documents for Reference of Previous Approval		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** **DML Certificate** Fuxin Long Rui Pharmaceutical Co., Ltd Valid Till: 17-Jan-2017 Linagliptin: **DML Certificate of** Manufacturer: Ruyuan Hec Pharm Co., Ltd Valid Till: October-07-2026 **Metformin HCl:** **DML Certificate** of Aarti Drugs Limited Valid Till: 20-March-2024		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** **Invoice** Invoice Num: HN210805-J Quantity: 25 kgs x 2 Batch: H-E-20210605-D01-E06-01 Mfg Date: Aug-06-2021 Exp Date: Aug-05-2023 **DRAP Attestation date: 03-09-2021** **Linagliptin:** **Invoice** Invoice Num: WIS200315 Quantity: 1 kgs Batch: C/0117/20/2675 (LGLT-RD202011202) **DRAP Attestation date: 18-01-2021** **Metformin HCl:** **Invoice** Invoice Num: EXP/1344/21 22 Quantity: MEF/11072137 : 25 kgs MEF/11072155 : 25 kgs Batch: MEF/11072137 MEF/11072155 **DRAP Attestation date: 06-08-2021**		
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.	Firm has submitted valid DML# Liao 20150233
	Empagliflozin	
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted
	Linagliptin	
3.2.S.4.3	• Performance of specificity parameter shall be submitted for analytical method verification studies. • 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.	• Submitted. • In system suitability test the diluted portion of test sample can be used as standard to assure system precision i.e., repeatability at LOD or LOQ level which ensure the system is précised at LOD or LOQ level.
3.2.P.1	• Clarification shall be submitted for the achievement of desired label claim of Empagliflozin & Linagliptin via active coating while submitted batch formulation does not declare any extra contents of coating solution.	• Provided formulation in "Description & Composition" depicts quantities in mg per tablet. Extra contents (10%) of coating solution for achieving the desired label claim are mentioned in the "Manufacturing Process Development" in Pharmaceutical development report (3.2.P.2).
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. • Justification shall be submitted for not performing tests of water content and arginine content in Pharmaceutical equivalence studies as recommended by the innovator product literature review from reference regulatory authorities.	• L-Arginine is used as a stabilizer for Linagliptin in the formulation and the quantity is taken on the basis of patent – WO 2017/093419 Al. Applicant of the patent: BOEHRINGER INGELHEIM INTERNATIONAL. • Submitted. • Firm has submitted revised the protocol and report for pharmaceutical equivalence studies along with performance of test of water content and content of arginine.
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.	• We, The Searle Company Limited has revised PD (Product Development) and to incorporate particle size as critical quality attributes however we confirm that consistent particle size is received from lot to lot.
3.2.P.5.1	• Justification shall be submitted for not including tests of arginine content in drug product specifications as recommended by the innovator product literature review from reference regulatory authorities.	Firm has submitted revised specifications and drug product method for the test of L-arginine content and moisture content test.

3.2.P.5.3	• Performance of specificity parameter shall be submitted for analytical method validation studies.	Submitted.
3.2.P.5.4	Justification shall be submitted for not performing tests of arginine content in drug product batch analysis as recommended by the innovator product literature review from reference regulatory authorities.	Firm has submitted revised specifications and drug product method for the test of L-arginine content and moisture content test.
3.2.P.8.3	• Justification shall be submitted for not including tests of arginine content in stability studies.	Firm has submitted revised stability protocol including test of L-arginine content and moisture content test.
2.3.R	• Complete batch manufacturing record of trial batches shall be submitted.	Submitted.

Decision: Registration Board approved the applications of EMTRO XR 12.5/2.5/1000mg Tablets, EMTRO XR 25/5/1000mg Tablets, EMTRO XR 10/5/1000mg Tablets & EMTRO XR 5/2.5/1000mg Tablets. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications for each strength 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.**

Case No. 02 Registration application submitted on form 5F for New Drug Manufacturing License:

17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals. Plot No K/201, S.I.T.E (SHW) Phase II, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals. Plot No K/201, S.I.T.E (SHW) Phase II, Karachi, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 05-01-2022 is provided)
	GMP status of the firm	New license granted on 22/02/2021 Capsule (General) section approved.
	Evidence of approval of manufacturing facility	New license granted on 22/02/2021 Capsule (General) section 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 27132 dated 26-09-2022
	Details of fee submitted	Rs.30,000/- dated 21-07-2022
	The proposed proprietary name / brand name	**Throtsin 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Azithromycin……250mg
	Pharmaceutical form of applied drug	Capsule contained in Alu Alu blister
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP

	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA
	For generic drugs (me-too status)	Azomax of M/s AGP
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceuticals Co., LTD, No.9 xingye street, Shijiazzhuang economic and technological development zone, Hebei province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, 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 of Drug Substance (Conditions & duration of 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
	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. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product. Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. Firm has further performed comparative dissolution profile (CDP) testing as per the in three dissolution mediums. The results of CDP also demonstrates similarity of the developed formulation in terms of release profile from the comparator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Guolong Pharmaceuticals Co., LTD China
API Lot No.	220207001
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	08-2021	08-2021	08-2021
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)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Drug Manufacturing License of Hebei Guolong Pharmaceutical Co. Ltd. (No. JI20150058) issued by Hebei Provincial Drug Administration dated 22-07-2020. The certificate is valid till 21-07-2025.
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.	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)	N/A

Evaluation by PEC:

Sr.#	Observations	Firm's response
1	Provide analytical method verification studies including specificity, precision and accuracy for drug substance performed by drug product manufacturer.	Submitted.
2	Submit detail analytical method used for drug product instead of submitted copy of pharmacopoeial monograph.	Firm has submitted drug product analytical procedure.
3	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: • 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). • Complete batch manufacturing record of stability batches.	Frim has submitted following: • Copy of License to import drugs for clinical trial issued by AD I&E DRAP Karachi for import of Azithromycin 10 kg. • Copy of commercial invoice attested by AD I&E DRAP, Karachi dated 18-11-2021 for import of Azithromycin 10Kg. • Batch manufacturing record of three stability batches. • Copy of Drug Manufacturing License of Hebei Guolong Pharmaceutical Co. Ltd. (No. JI20150058) issued by Hebei Provincial Drug Administration valid till 21-07-2025.

Decision: Approved.

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

Case No. 03: Routine Registration application of Human drugs on Form 5F (Local manufacturing)

a. New cases

18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 671 dated 07/01/2022
	Details of fee submitted	PKR 30,000/-: dated 16/12/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 10mg + 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin (immediate release)……10mg Metformin HCl (extended release)…..1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet 10mg/1000mg by Boehringer Ingelheim, USFDA, UK & Health Canada Approved.
	For generic drugs (me-too status)	Erli Plus Tablets 10mg + 1000mg by Pharmevo Reg. No. 105274
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Innovator product that is Synjardy XR Tablet 10mg + 1000mg by Boehringer Ingelheim, USA by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Synjardy XR Tablet 10mg + 1000mg by Boehringer Ingelheim, USA 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	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI
Description of Pack (Container closure system)	Alu-Alu blisters packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

		Real Time: 0, 3, 6 (Months)		
Batch No.		NPD-T-1614-S	NPD-T-1623-S	NPD-T-1624-S
Batch Size		2500 tablets	5000 tablets	5000 tablets
Manufacturing Date		03-08-2021	24-08-2021	24-08-2021
Date of Initiation		03-09-2021	03-09-2021	03-09-2021
No. of Batches		03		
Administrative Portion				
I	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.		
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.		
III	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.		
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.		
19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**		
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Dy. No. and date of submission	Dy. No. 2526 dated 26/01/2022		
	Details of fee submitted	PKR 30,000/-: dated 16/12/2021		
	The proposed proprietary name / brand name	**Empator-M XR Tablet 5mg + 1000mg**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin (immediate release)…….5mg Metformin HCl (extended release)…..1000mg		

	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet 5mg/1000mg by Boehringer Ingelheim, USFDA, UK & Health Canada Approved.
	For generic drugs (me-too status)	Erli Plus Tablet 5mg + 1000mg by M/s Pharmevo (Pvt.) Ltd., Reg. No. 105273
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	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	Pharmaceutical Equivalence is established against the

	dissolution profile	Innovator product that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA 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	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI
Description of Pack (Container closure system)	Alu-Alu blisters packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	NPD-T-1656-S	NPD-T-1660-S	NPD-T-1661-S
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	13-09-2021	18-09-2021	18-09-2021
Date of Initiation	29-09-2021	29-09-2021	29-09-2021
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.
III	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.

IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.
20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 670 dated 07/01/2022
	Details of fee submitted	PKR 30,000/-: dated 29/11/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 12.5mg + 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin (immediate release)…….12.5mg Metformin HCl (extended release)…….1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet (5mg/1000mg, 10mg/1000mg, 12.5mg/1000mg, 25mg/1000mg) USFDA Approved.
	For generic drugs (me-too status)	Erli Plus XR Tablet 12.5/1000mg by M/s Pharmevo (Pvt.) Ltd., (Reg. No. 105275)
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	. Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence IS established against the Innovator product that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Synjardy XR Tablet 5mg + 1000mg by Boehringer Ingelheim, USA 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	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI
Description of Pack (Container closure system)	Alu-Alu blisters packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1626-S	NPD-T-1660-S	NPD-T-1661-S
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	24-08-2021	18-09-2021	18-09-2021
Date of Initiation	29-09-2021	29-09-2021	29-09-2021
No. of Batches	03		

Administrative Portion

I	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.
II	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.
III	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by DRAP Karachi.
IV	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
V	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
VI	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Remarks of Evaluator-I:

Sr. No.	Observations	Response
1	The submitted stability data is till 3rd month time point, please provide stability study data till 6th month time point.	The firm has referred to the earlier submitted stability data of 6th month time point for all three strengths.
2	• Provide complete batch manufacturing record for the applied product along with the calculations for potency adjustment considering the assay value of the drug substance on As-is basis. • Provide detail of manufacturing method for the applied product.	Complete batch manufacturing record has been submitted for three batches of each strength. It is evident from the submitted batch processing record that instead of dispensing the whole API coating solution in excess to overcome the process loss, firm has used 100% excess of Empagliflozin only.

Justification of Overage:
Empator-M 25mg + 1000mg XR Tablet was developed with reference to the Innovator product, **Synjardy 25mg + 1000mg XR Tablet** of MSD, which contains extended-release core of Metformin HCl (1st API) and API coating of immediate release Empagliflozin (2nd API).

The coating process itself, is inevitable to process loss, due to which it is required to add an excess amount of raw materials in the coating solution so that the final landing quantity of API on the core tablet complies with the claimed amount.
Similar case was observed at development stage, during the coating of Empagliflozin on Metformin core, the quantity of coating solution was gradually increased by hit n trial to comply the landing quantity of API on the tablet in accordance with the label claim.
With reference to the ***WHO Annex 3 Pharmaceutical development of multisource (generic) finished pharmaceutical products***, the excess quantity of API coating solution is justified as the excess is lost during the coating process and it was completely utilized to achieve the required quantity on the tablet after Drug loading stage.
The assay results of API Empagliflozin at release testing and throughout the stability studies, are within the label claimed amount, making it evident that the excess amount of API coating solution was lost during the coating process and was not part of the finished dosage form. The **Assay** results of the stability studies are given as reference:

Justification of dissolution profile:
Martin Dow Limited has developed following strengths of Empagliflozin + Metformin HCl XR tablets for new product registration applications,
Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 12.5 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 10 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 25 mg + Metformin HCl 1000 mg XR Tablet
As per the ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products
Bracketing can be applied to studies with multiple strengths of identical or closely related formulations. Examples include but are not limited to (1) capsules of different strengths made with different fill plug sizes from the same powder blend, (2) tablets of different strengths manufactured by compressing varying amounts of the same granulation, and (3) oral solutions of different strengths with formulations that differ only in minor excipients (e.g., colourants, flavourings).
Martin Dow has perfomed Extended-release dissolution profile at core stage before coating of Empator 12.5/1000mg XR and Empator 5/1000mg XR Tablet tablet, meanwhile establishing dissolution profile of Empator 25/1000mg XR Tablet of core stage as per the method of bracketing, and later on batches were found to have the satisfactory results with extended release dissolution profile of Metformin HCl specification at coated stage.

Decision: Registration board deferred the applications of Empator-M XR Tablet 10mg + 1000mg, Empator-M XR Tablet 5mg + 1000mg & Empator-M XR Tablet 12.5mg + 1000mg for following reasons:

- **Scientific justification on the basis of performance based data for using 100% excess of drug substance in the active coating of Empagliflozin.**
- **Submission of any performance based data to justify that 100% excessive Empagliflozin is required to overcome the process loss during active coating.**
- **Justification for referring the "ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products" for skipping the in-process test of dissolution of Metformin extended release core, since the cited guideline is intended to address recommendations on the application of bracketing and matrixing to stability studies.**

b. Deferred cases:

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh**
	Name, address of Manufacturing site.	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on 13-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable 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 32576 dated 30-11-2021
	Details of fee submitted	Rs.50,000/- dated 29-03-2021
	The proposed proprietary name / brand name	**Parmol 1000mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol ……. 1000mg
	Pharmaceutical form of applied drug	Parenteral (Injectable)
	Pharmacotherapeutic Group of (API)	Analgesic/Antipyretic
	Reference to Finished product specifications	Manufacturer's Spec
	Proposed Pack size	1's x 100ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Falgan infusion of M/s Bosch
	Name and address of API manufacturer.	ANHUI BBCA LIKANG PHARMACEUTICAL CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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 stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is BOFALGAN 1g/100ml Solution for infusion by **BOSH PHARMACEUTICALS (PVT) LTD** by performing quality tests (Identification, Assay, sterility & volume variation

		N/A
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA

Manufacturer of APIs	Anhui BBCA Likang Pharmaceutical CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China		
API Lot No.	202002047A		
Description of Pack (Container closure system)	Type III 100 ml glass vial pack in unit carton is used as primary packaging (1 x1 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.	PI-001	PI-001	PI-001
Batch Size	3500 Vials	3500 Vials	3500 Vials
Manufacturing Date	08-2021	08-2021	08-2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	**Documents To Be Provided**	**Status**
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.	--
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 data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section	**Observation**	**Firm's response**
1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.P.8.3	• Documents confirming procurement of drug substance shall be submitted. • Complete batch manufacturing record of	• Copy of commercial invoice no. 20NVT-090 attestedby AD DRAP I&E Karachi dated 27-03-

	stability batches shall be submitted.	2020 for import of 1000 Kg of Paracteamol in name of M/s Inventor.

Decision of 323rd meeting: Deferred for submission of following:

- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.
- Complete batch manufacturing record of stability batches.

Firm's reply: Firm has submitted following:

- Copy of DML# 20160002issued by Anhui Provincial Drug Administration, valid till 31-12-2025.
- Batch manufacturing record for the three stability batches.
- Analytical method verification studies for the drug substance performed by M/s Inventor.

Decision of 326th meeting: 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.

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

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi

22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Standard Drug Company. E-6A, S.I.T.E Hyderabad**
	Name, address of Manufacturing site.	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on 13-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable 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 32576 dated 30-11-2021
	Details of fee submitted	Rs.50,000/- dated 29-03-2021
	The proposed proprietary name / brand name	**Strapals 1000mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol ……. 1000mg
	Pharmaceutical form of applied drug	Parenteral (Injectable)
	Pharmacotherapeutic Group of (API)	Analgesic/Antipyretic
	Reference to Finished product specifications	Manufacturer's Spec
	Proposed Pack size	1's x 100ml

	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Falgan infusion of M/s Bosch
	Name and address of API manufacturer.	ANHUI BBCA LIKANG PHARMACEUTICAL CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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 stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is BOFALGAN 1g/100ml Solution for infusion by **BOSH PHARMACEUTICALS (PVT) LTD** by performing quality tests (Identification, Assay, sterility & volume variation N/A
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA	
Manufacturer of APIs	Anhui BBCA Likang Pharmaceutical CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China
API Lot No.	202002047A
Description of Pack (Container closure system)	Type III 100 ml glass vial pack in unit carton is used as primary packaging (1 x1 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.	PI-001	PI-001	PI-001
Batch Size	3500 Vials	3500 Vials	3500 Vials
Manufacturing Date	08-2021	08-2021	08-2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
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.	--
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 data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section	Observation	Firm's response
1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.P.8.3	• Documents confirming procurement of drug substance shall be submitted. • Compete batch manufacturing record of stability batches shall be submitted.	Copy of commercial invoice no. 20NVT-090 attested by AD DRAP I&E Karachi dated 27-03-2020 forimport of 1000 Kg of Paracteamol in name of M/s Inventor.

Decision of 323rd meeting: Deferred for submission of following:

- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.
- Complete batch manufacturing record of stability batches.

Firm's reply: Firm has submitted following:

- Copy of DML# 20160002issued by Anhui Provincial Drug Administration, valid till 31-12-2025.
- Batch manufacturing record for the three stability batches.
- Analytical method verification studies for the drug substance performed by M/s Inventor.

Decision of 326th meeting: 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.

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

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi

23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s MartinDow Limited, plot no. 37, Sector 19, Korangi Industrial area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33103 dated 17/12/2021
	Details of fee submitted	PKR 30,000/-: dated 29/11/2021
	The proposed proprietary name / brand name	**Empator-M XR Tablet 25mg+1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated, extended release tablet contains: Empagliflozin (immediate release)……..25mg Metformin HCL (extended release)…….1000mg
	Pharmaceutical form of applied drug	Film coated, extended release tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	14's, 28's
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR tablet by Hilton Pharma
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 85/2020-DRAP(K) issued on the basis of inspection conducted on 07/05/2019
	Section approval	Table tgeneral section (Regularised)
	Name and address of API manufacturer.	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to

		nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substances (i.e Metformin & Empagliflozin).
	Stability studies	Stability study conditions: Empagliflozin: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: EGLZ-20160501, EGLZ-20160502, EGLZ-20160503 Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: 9002ML2RMI, 9003ML2RMI, 9004ML2RMI
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies have been submitted against the innovator's product that is Synjardy XR tablet 25/1000mg mfg by Boehringer Ingelheim USA (Batch number: 3189877) by performing all the quality tests. Comparative dissolution profile is submitted agaisn the innovator's product that is Synjardy XR Tablet (25/1000mg) in 0.1N HCL, Phosphate Buffer and Acetate Buffer. F2 values are in acceptable range.
	Analytical method validation/verification of product	Analytical method verification / validation studies for drug substance as well as for drug product is submitted.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** RUYUAN HEC Pharm Co., Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, P.R. China **Metformin HCl:** IPCA Laboratories Limited, H-4, MIDC, Waluj Aurangabad431136 Maharahtra India.		
API Lot No.	Empagliflozin: EGLZ-RD202004002 Metformin: 21060ML2ARMI		
Description of Pack (Container closure system)	Alu-Alu blisters packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1573-S	NPD-T-1616-S	NPD-T-1617-S
Batch Size	4000 tablet	4000 tablet	4000 tablet
Manufacturing Date	07/07/2021	04/08/2021	07/07/2021
Date of Initiation	17/08/2021	17/08/2021	17/08/2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Empator-M tablet 5mg+500mg (Empaglilozin + Metformin HCl) approved in 312th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP Certificate for RUYUAN HEC Pharm Co., Ltd. (Certificate: 2018024) issued by Shaoguan Food and Drug Administration & valid upto 04-12-2021 is submitted. **Metformin HCl:** Copy of GMP certificate No. New-WHO-GMP/Cert/AD/67318/2018/11/24741 issued on 28/08/2018 valid till 27/08/2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of attested invoice (invoice# WIS200034) Dated: 16/04/2020 dy. No. 499 dated 04/05/2020. **Metformin HCl: Copy of attested** Invoice No. MEG2122/1630115 dated 02/04/2021 (diary No. 4247 dated 07/04/2021) imported from IPCA Laboratories limited attested by 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)	Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted.

Remarks of Evaluator-I:

Sr. No.	Observations	Response
1	The submitted stability data is till 3rd month time point, please provide stability study data till 6th month time point.	The firm has submitted stability summary sheets till 6 months for accelerated and long term stability studies along with the relevant documents.
2	As per submitted dossier, titration method has been used for assay estimation for Metformin HCl while according to latest edition of USP, HPLC method should be used for assay testing, please clarify.	*"The method used for assay estimation of Metformin for finished product by FPP manufacturer is HPLC as per latest edition of USP. API manufacturer has used titration method for assay estimation owing to the previous version of USP monograph".*
3	Provide complete batch manufacturing record for the applied product.	Complete batch manufacturing record is submitted.
4	As per submitted dossier, dissolution tests for Metformin core before coating has not been performed. Clarification is required for not establishing the dissolution profile for the tablet core.	*The Dissolution testing for Metformin HCl was performed at core stage before coating and results were well within specified limits. Since Metformin HCl in all strength have same label claim and same formulation, therefore dissolution profile is performed on film coated stage on risk basis. Satisfactory initial and stability results are also evident on Metformin HCl dissolution performance.* *Following core stage results are also attached herewith.* *Batch No. NPD-T-1108-T (Empagliflozin 5mg + Metformin HCl 1000 mg XR Tablet)* *Batch No. NPD-T-1107-T (Empagliflozin 12.5mg + Metformin HCl 1000 mg XR Tablet)*

5	Provide detail of manufacturing method for the applied product.	The firm has submitted complete batch manufacturing record for the applied product.

6. Scientific justification is required regarding addition of 100% overage for Empagliflozin for compensating the loss during coating.

Response:

Empagliflozin + Metformin HCl 25 + 1000 mg XR tablet is an API (Empagliflozin) coated tablet. Hence, the API is part of the coating suspension. As per label claim, 25 mg of Empagliflozin is coated on the tablet as mentioned in the Batch Production Record of Empagliflozin + Metformin HCl 25 + 1000 mg XR tablet, pp# 25 and is evident through the tablet weight that is 1479.0 mg, pp #43 95mg was coated on the tablet of 1384.0 mg thus taking it to 1479.00mg. Breakup is given below:

API Coating			
S.No.	*Raw Material*	*Quantity/tablet*	*Quantity/Batch*
1	*Empagliflozin*	*25.000 mg*	*250.000 g*
2	*Sheffcoat D white 5Y00692*	*42.000 mg*	*420.000 g*
3	*Talc*	*3.000 mg*	*30.000 g*
4	*Polysorbate 80 (Tween 80)*	*20.000 mg*	*200.000 g*
5	*Polyethylene Glycol 6000*	*5.000 mg*	*500.000 g*

Thus, no overages of the API are added which can be seen via the content increase of tablet before and after API coating mentioned above.

- *The 100% excess quantity mentioned in the BPR is for the clarity of the reviewer and the document itself.*
- *Excess quantity was added in coating material i.e., Sheffcoat D white 5Y00692, Polyethylene Glycol 6000, Talc, Polysorbate 80 (Tween 80) along with it is the **API Empagliflozin** to compensate for the process loss faced while Coating operation is being carried out, as it is an API coated tablet.*

*As it is understood that losses are observed/experienced during coating and thus extra quantities are added as a recompense. These extra quantities do not become part of the final film coated product, as is evident in the **Assay** results of **Empagliflozin** which are well within limits as per label claim.*

Decision of 322nd meeting: Registration Board deferred the case for;

- Scientific justification regarding addition of 100% overage for Empagliflozin for compensating the loss during coating.
- Clarification for not establishing the dissolution profile of the extended release core tablet before coating.

Firm's response:

Justification of Overage:

Empator-M 25mg + 1000mg XR Tablet was developed with reference to the Innovator product, **Synjardy 25mg + 1000mg XR Tablet** of MSD, which contains extended-release core of Metformin HCl (1st API) and API coating of immediate release Empagliflozin (2nd API).

The coating process itself, is inevitable to process loss, due to which it is required to add an excess amount of raw materials in the coating solution so that the final landing quantity of API on the core tablet complies with the claimed amount.

Similar case was observed at development stage, during the coating of Empagliflozin on Metformin core, the quantity of coating solution was gradually increased by hit n trial to comply the landing quantity of API on the tablet in accordance with the label claim.

With reference to the ***WHO Annex 3 Pharmaceutical development of multisource (generic) finished pharmaceutical products***, the excess quantity of API coating solution is justified as the excess is lost during the coating process and it was completely utilized to achieve the required quantity on the tablet after Drug loading stage.

The assay results of API Empagliflozin at release testing and throughout the stability studies, are within the label claimed amount, making it evident that the excess amount of API coating solution was lost during the coating process and was not part of the finished dosage form. The **Assay** results of the stability studies are given below as reference:

Batch No. NPD-T-1616-S			
Real Time			
Assay (Empagliflozin**)**	**0**	**3M**	**6M**
90.0 %-110.0 %	101.5 %	101.7 %	97.8 %
Accelerated			

90.0 %-110.0 %	101.5 %	101.9 %	98 %

Justification of dissolution profile:

Martin Dow Limited has developed following strengths of Empagliflozin + Metformin HCl XR tablets for new product registration applications,

Empagliflozin 5 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 12.5 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 10 mg + Metformin HCl 1000 mg XR Tablet
Empagliflozin 25 mg + Metformin HCl 1000 mg XR Tablet

As per the ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products

Bracketing can be applied to studies with multiple strengths of identical or closely related formulations. Examples include but are not limited to (1) capsules of different strengths made with different fill plug sizes from the same powder blend, (2) tablets of different strengths manufactured by compressing varying amounts of the same granulation, and (3) oral solutions of different strengths with formulations that differ only in minor excipients (e.g., colourants, flavourings).

Martin Dow has perfomed Extended-release dissolution profile at core stage before coating of Empator 12.5/1000mg XR and Empator 5/1000mg XR Tablet tablet, meanwhile establishing dissolution profile of Empator 25/1000mg XR Tablet of core stage as per the method of bracketing, and later on batches were found to have the satisfactory results with extended release dissolution profile of Metformin HCl specification at coated stage.

Decision: Registration board deferred the application for following reasons:

- **Scientific justification on the basis of performance based data for using 100% excess of drug substance in the active coating of Empgaliflozin.**
- **Submission of any performance based data to justify that 100% excessive Empagliflozin is required to overcome the process loss during active coating.**
- **Justification for referring the "ICH Q 1 D guideline of Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products" for skipping the in-process test of dissolution of Metformin extended release core, since the cited guideline is intended to address recommendations on the application of bracketing and matrixing to stability studies.**

24.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals Limited. Plot No. 65, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, Punjab, Pakistan
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30772 dated 10-11-2021
	Details of fee submitted	Rs.75,000/- dated 29-10-2021
	The proposed proprietary name / brand name	**Maxflow-S 0.4mg/6mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer modified release tablet contains: Solifenacin succinate…….6mg (Corresponding to 4.5mg of Solifenacin base) Tamsulosin hydrochloride…….0.4mg (Corresponding to 0.37mg of Tamsulosin base)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antimuscarinics/Alpha-blockers
	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Vesomni Tablet by M/s Astellas Pharma Ltd., EMA Approved.
	For generic drugs (me-too status)	Tamsolin -S by M/s Getz Pharma
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022.
	Name and address of API manufacturer.	M/s Alphamed Formulations Pvt. Ltd Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Solifenacin Succinate & Tamsulosin HCl is not present in Pharmacopoeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Tamsulosin HCL Batches: (8000173-039(A), 8000173-045(A), 8000173-046(A)) Solifenacin Succinate Batches: (8000173-039(B), 8000173-045(B), 8000173-046(B))
	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 Vesomni Tablet by M/s Astellas Pharma Ltd, UK by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Vesomni Tablet by M/s Astellas Pharma Ltd, UK in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Alphamed Formulations Pvt. Ltd.

	Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India		
API Lot No.	Tamsulosin HCl: 8000173-041(A) Solifenacin Succinate: 8000173-041(B)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T5-01	T5-02	T5-03
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	09-2017	09-2017	09-2017
Date of Initiation	10-10-2017	10-10-2017	10-10-2017
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 30/08/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of Invoice, Diary No. 2142 dated 04/08/2017 is submitted wherein the permission to import API Tamsulosin HCl and Solifenacin Succinate is granted. • Invoice No. 034/2017-18 attested by AD I&E dated 04-08-2017.
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(Ammar):

Subsequently firm has submitted stability studies data of 2 commercial batches along with full fee of Rs. 75,000/- vide deposit slip# 986205168101. Details of the commercial batches data is as under:

Manufacturer of API	M/s Alphamed Formulations Pvt. Ltd. Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India
API Lot No.	Tamsulosin HCl: AT0018-002 Solifenacin Succinate: AT0019-003
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

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

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 30/08/2022.
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.	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
Pharmaceutical equivalence and CDP Studies data in three dissolution mediums of pH 1.2, 4.5 & 6.8 has been submitted against the Tamsolin-S tablet pf M/s Getz Pharma		

Section#	Observations	Firm's response
3.2.S.4 (Tamsulosin HCl)	• Submitted drug substance specifications of Tamsulosine granules does not include test of dissolution hence it's not evident that the Tamsulosine granules are modified release or otherwise. Justification shall be submitted in this regard. • Submitted COA from both drug substance and drug product manufacturer does not declare the Tamsulosine granules as "modified release". • Justification shall be submitted for using Tamsulosine granules 0.178% w/w% for drug product formulation without establishing its dissolution profile.	• With reference to the control of drug substance, API manufacturer has tested the dissolution against the RLD Vesomni, but did not include the test in release specifications. Moreover, FPP Manufacturer has included the Dissolution Testing of Tamsulosin Granules at finished product stage, that shows the granules release is modified. • Dissolution testing is not included in the release specification. However, modified release of tamsulosin granules is declared in the label claim of the Finished Product. • Dissolution profile of the granules established at FPP stage as evident from the Product testing Method and CDP.

3.2.P.1	• Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.	Label claim of the tablet is as follow: Each bilayer modified release tablet contains: Solifenacin succinate… 6mg (Corresponding to 4.5mg of Solifenacin base) (Immediate release layer) Tamsulosin hydrochloride….0.4mg (Corresponding to 0.37mg of Tamsulosin base) (Modified release layer)
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies till 12 hours' time point only, whereas the drug product specifications mention the last time point as of 16hrs.	For Tamsulosin in CDP, release NLT 80% achieved in 12hours therefore next time point was not included in consideration.
3.2.P.5	• Justification shall be submitted for applying speed of 100rpm with USP Apparatus II in the dissolution test with reference to the provisions of USP general chapter <1092>.	According to USP General Chapter <1092>, Please consider the following, *"100 rpm may be used with Apparatus 2, especially for extended-release products. Decreasing or increasing the apparatus rotation speed may be justified if to achieve an in vitro–in vivo correlation (IVIVC) the resulting profiles better reflect in vivo performance, or if the method results in better discrimination without adversely affecting method variability."*
3.2.P.8.3	• Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.	Copy of letter issued by AD I& E DRAP Islamabad, dated 28-10-2021, permitting import of Solifenacin 6% granules (25Kg) & Tamsulosin HCl 0.178% granules (50 Kg)
	• Submitted BMRs does not reflect the dispensing of Magnesium stearate, whereas the composition submitted in section 3.2.P.1 includes magnesium stearate. • Dispensed quantity of Tamsulosine HCl granules & Solifenacin granules, shall be justified against the potency determined during drug substance analysis.	• Mg. stearate in Section 3.2.P.1 is approximately 2% of the formulation which is used to increase the flow properties of granules only if required and that would be of Pharmacopeial Grade (BP), if used. Therefore, submitted BMR does not includes the Mg. Stearate. • Potency determined during the Analysis of both the drug substance is more than 100%, that's why Potency is considered equivalent to 100% while dispensing of Drug substance.

Decision of 323rd meeting: Deferred for following:

- Justification for claiming "Tamsulosine HCl granules" as modified release since no such declaration has been maned in drug substance specifications and COA.
- Scientific justification from drug substance manufacturer for not including test of "Dissolution" in the specifications of "Tamsulocin HCl granules" for establishing the modified release profile.
- Scientific justification from drug product manufacturer for not establishing dissolution profile of "Tamsulosine HCl granules" vide performance of dissolution test before using them as in the drug product formulation.
- Capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad

Firm's response: Firm has submitted as under:

i. Tamsulosin HCl granules contains 0.178% active while other is excipient for modified release profile, it is the restricted / hidden part of DMF.

ii. Modified release profiles can be achieved upon compression of granules to tablet and in tablets; dissolution has been performed by drug product manufacturer.

iii.	We have performed testing as per manufacturer's method of analysis and dissolution profile can be analysed after compression of granules to tablets. The granules contain polymer and its function is effective after compression.	
Decision of 326th meeting: Deferred for following: • **Submission of restricted / hidden part of DMF of "Tamsulosine HCl granules" from the drug substance manufacturer.** • **Justification for claiming "Tamsulosine HCl granules" at drug substance stage as modified release since firm has submitted that Modified release profiles can be achieved upon compression of granules into tablet.**		
25.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JASM Pharmaceuticals (Pvt) Ltd** **Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.**
	Name, address of Manufacturing site.	M/s JASM Pharmaceuticals (Pvt) Ltd Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	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 availability of manufacturing section.	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup, Cream Ointment (General Sections) Approved
	Dy. No. and date of submission	Dy. No 32161 dated 24-11-2021
	Details of fee submitted	Rs.30,000/- dated 04-10-2021
	The proposed proprietary name / brand name	**Celozin 125mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ciprofloxacin……125mg
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	60 ml / bottle or 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)	Mytil suspension of M/s Wilson
	GMP status of the Finished product manufacturer	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup , Cream Ointment (General Sections) Approved
	Name and address of API manufacturer.	M/s **Vision Pharmaceuticals (Pvt) Limited.** 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 has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, 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 Novidat Suspension 125 mg/5ml by Sami Pharmaceuticals.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s **Vision Pharmaceuticals (Pvt) Limited.** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.		
API Lot No.	CPX1250		
Description of Pack (Container closure system)	90 ml / bottle packed in a Unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	P43	P45	P47
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	04-05-2021	05-05-2021	06-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No.F.3-26/2019-Addl.Dir.(QA&LT-I) Issued By DRAP Valid till 10/02/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Manual record has been submitted with one reading in a day
26.	**Name, address of Applicant / Marketing Authorizatsion Holder**	**M/s JASM Pharmaceuticals (Pvt) Ltd** **Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.**
	Name, address of Manufacturing site.	M/s JASM Pharmaceuticals (Pvt) Ltd Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	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 availability of manufacturing section.	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup, Cream Ointment (General Sections) Approved
	Dy. No. and date of submission	Dy.No 32162 dated 24-11-2021
	Details of fee submitted	Rs.30,000/- dated 04-10-2021
	The proposed proprietary name / brand name	**Celozin 250mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ciprofloxacin…….…250mg
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	60 ml / bottle or 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)	Mytil suspension of M/s Wilson
	GMP status of the Finished product manufacturer	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup , Cream Ointment (General Sections) Approved
	Name and address of API manufacturer.	M/s **Vision Pharmaceuticals (Pvt) Limited.** 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 has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, 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 Novidat Suspension 250 mg/5mL by Sami Pharmaceuticals.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s **Vision Pharmaceuticals (Pvt) Limited.** Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan.		
API Lot No.	CPX1250		
Description of Pack (Container closure system)	90 ml / bottle packed in a Unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	P44	P46	P48
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	05-05-2021	05-05-2021	06-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No.F.3-26/2019-Addl.Dir.(QA&LT-I) Issued By DRAP Valid till 10/02/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Manual record has been submitted with one reading in a day

Firm's response:

Remarks of Evaluator:

Section#	Observation	Firm's response
3.2.S.4.2	• Justification shall be submitted for applying UV spectrophotometric method for the analysis of Ciprofloxacin taste masked pellets. • The dissolution parameters applied for the analysis of Ciprofloxacin pellets are different form that recommended by USP monograph of Ciprofloxacin for oral suspension.	• Firm has submitted that we followed the substance manufacturer analytical method validated and then used for the analysis of substance. • In finished product specifications followed the USP monograph and their dissolution parameters for oral suspension.
3.2.P.1	• Clarification shall be submitted regarding proposed excipients, whether they are part of the formulation or diluent.	Firm has submitted that the proposed excipients are part of diluents.
3.2.P.2.2.1	• Details of reference product, against which Pharmaceutical equivalence studies have been performed, shall be submitted. • Justification shall be submitted for not performing CDP.	• Firm has submitted comparative dissolution study reports for both applied strengths against the Novidat suspension of M/s Sami Pharmaceuticals.
3.2.P.2.5	• Justification shall be submitted for preservative effectiveness studies, since no preservative has been proposed in applied formulation.	• Firm has declared it as a clerical mistake.
3.P.2.6	• Proposed diluent is not as recommended by the innovator product.	• Firm has submitted the revised information wherein diluent as recommended by innovator has been mentioned, while no analytical data has been reported for the compatibility studies.
3.2.P.3.3	• The manufacturing process mentions the steps of tablet manufacturing.	• Firm has submitted revised description of manufacturing process for applied dosage form.
3.2.P.3.5	• Submitted process validation protocol does not mention any details of critical process parameters and sampling plan.	• Firm ha submitted revised process validation protocol wherein details of critical process parameters and sampling plans are still not mentioned.
3.2.P.5.2	• Submitted analytical procedure does not mention any details for dissolution test. • Evidence of availability of HPLC equipped with the autosampler, capable of maintaining 10°C temperature shall be submitted.	• Firm has submitted revised analytical procedure including dissolution test. • Firm has submitted HPLC report wherein Tray temperature for autosampler has been mentioned as 10°C.

3.2.P.8	• Submitted raw data sheet for dissolution test does not declare the determination of density of reconstituted suspension, as required by the USP monograph, also the calculation formula has not been mentioned. • Raw data for the Assay test has not been submitted. • In-use stability data shall be submitted.	• Firm has submitted calculation formula along with values of various factors, density etc. • The results of the dissolution test reported in the raw data sheet does not coincide with the provided formula. • Raw data sheets for assay test have been submitted.
	• Section 3.2.P.1 mentions water in formulation, whereas submitted BMRs does not declare use of water in the formulation. • Evidence of reference product shall be submitted wherein the excipients proposed in applied formulation have been used.	

Decision of 316th meeting: Registration Board deferred both the applications of "Celozin 250mg/5ml Dry Suspension" & "Celozin 125mg/5ml Dry Suspension" for following:

- Submission of compatibility studies with the diluent as recommended by the innovator product.
- Clarification regarding manufacturing area where the proposed diluent will be manufactured.
- Submission of process validation protocol wherein details of critical process parameters and sampling plan shall have bene mentioned.
- Justification for the results of dissolution test since results of the dissolution test reported in the raw data sheet does not coincide with the provided calculation formula.
- Submission of fee of Rs.7,500 for correction/pre-approval change in the method of manufacture & drug product testing method, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Firm's reply:

Observations	**Firm's response**
Submission of compatibility studies with the diluent as recommended by the innovator product.	Firm has performed compatibility studies with the diluent as recommended by innovator product.
Clarification regarding manufacturing area where the proposed diluent will be manufactured.	Firm has referred to the oral liquid section for the preparation of diluent.
Submission of process validation protocol wherein details of critical process parameters and sampling plan shall have bene mentioned.	Submitted.
Justification for the results of dissolution test since results of the dissolution test reported in the raw data sheet does not coincide with the provided calculation formula.	Firm has submitted revised calculation formula against the raw data sheets for the performance of dissolution test.
Submission of fee of Rs.7,500 for correction/pre-approval change in the method of manufacture & drug product testing method, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted fee of Rs. 7.,500/- vide deposit slip# 23252609 & 326074755 for 125mg & 250mg strength respectively.

Decision: Registration Board deferred the applications Celozin 125mg/5ml Dry Suspension & Celozin 250mg/5ml Dry Suspension for further deliberation regarding requirement for the diluent for applied formulation.

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.

Agenda of Evaluator PEC-XI

Case No. 04; New application for registration of Human drugs on Form 5-F on export facilitation
Assistant director PR-I/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 29-12-2022 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

27.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	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 19-01-2022 based on inspection conducted on 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20200 dated: 15/06/2022
	Details of fee submitted	Rs. 30,000/- dated 23-06-2022 (Deposit silp#41842899)
	The proposed proprietary name / brand name	**Daplozmet XR 10/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….10mg Metformin hydrochloride (Extended release) ……..…500mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 10/500mg film coated Tablets, USFDA Approved.

	For generic drugs (me-too status)	Xiga-Met 10/500mg XR Tablet by M/s CCL Pharmaceuticals (Reg#112049)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** 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 of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, 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 has been established against the innovator brand that is XIGDUO XR 10/500mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the same brand that is XIGDUO XR 10/500mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range

	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.		
STABILITY STUDY DATA				
Manufacturer of API		**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.		**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 3 months Accelerated: 3 months		
Frequency		Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.		RD-21313	RD-21327	RD-21326
Batch Size		4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation		08-01-2022	08-01-2022	08-01-2022
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
7.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024		
9.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D) Dated 20-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s		

		Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
10.	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.
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 03 months is submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee	•
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?	•
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document	•
3.2.P.2	• Justification is required for using 5% (0.615mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation	•
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies	•
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted	•

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

28.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	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 19-01-2022 based on inspection conducted on 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20202 dated: 15/06/2022
	Details of fee submitted	Rs. 30,000/- dated 23-06-2022

		(Deposit silp#8069049838)
	The proposed proprietary name / brand name	**Daplozmet XR 10/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….10mg Metformin hydrochloride (Extended release) ……..…1000mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 10/1000mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 10/1000mg XR Tablet by M/s CCL Pharmaceuticals (Reg#110627)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, 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)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** 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 of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:**

		Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, 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 has been established against the innovator brand that is XIGDUO XR 10/1000mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the same brand that is XIGDUO XR 10/1000mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21166	RD-21225	RD-21282
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	08-2021	09-2021	10-2021
Date of Initiation	06-11-2021	06-11-2021	06-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui

		Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D) Dated 20-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches 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)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee	•
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?	•
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document	•
3.2.P.2	• Justification is required for using 5% (0.615mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation	•
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies	•
3.2.P.8	• Justification is required since submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed (22-11-2021) subsequent to the initiation of stability study (6-11-2021) for all batches	•

Decision: Registration Board was apprised that the letter of shortcoming has been initially shared with the firm hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Agenda of Evaluator PEC-XX

Case No: 01. **Priority consideration of Propofol applications due to its shortage in market**

M/s Ghani Brothers, Karachi vide letter dated 01-03-2023 has informed that they have applied for registration of Freefol-MCT 1% Injection 20ml Vial (Propofol 10mg/ml), manufactured by Daewon Pharm, Co Ltd, South Korea on 31-08-2022. The firm further informed that currently there is severe shortage of Propofol injection which is also an essential drug and also enclosed the minutes of 1st meeting of the Cabinet Committee on supplies of medicines and medical devices of Specialized Healthcare & Medical Education Department (SHC&ME), Govt. of Punjab held on 20-02-2023 in which it was discussed about shortage of medicines including Propofol Injection. The firm has requested to include the above subject mentioned product in the upcoming registration board meeting on priority basis, so that the product can be approved earliest possible to contribute in removing the shortage of Propofol injection from the market and serve the patients. In the light of above and on the directions of Chairman RB, following application(s) of Propofol are placed before the Board for its consideration:

29.	**Name, address of Applicant / Importer**	**M/s Ghani Brothers, 1st Floor, Karimjee Building, Opp HBL Bank, North Napier Road, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No: 094** **Address:**. 1st Floor, Karimjee Building, Opp HBL Bank, North Napier Road, Karachi, Pakistan **Address of Godown:** NA **Validity:**.28-04-2023 **Status:** License to sell drugs as wholesale **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	Daewon Pharm Co.,Ltd, 24 Jeyakgondan 1-gil Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	Daewon Pharm Co.,Ltd, 24 Jeyakgondan 1-gil Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea.
	Name of exporting country	South Korea
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized copy of CoPP certificate No 2021-A1-0028 and GMP certificate issued by Food and Drug Administration Republic of South Korea for Freefol MCT 1% Injection 20ml Vial (Propofol 10mg/ml). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 year.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of Sole Agency Agreement from Daewon Pharm Co. Ltd, South Korea. The letter species that the manufacturer appoints M/s Ghani Brothers. to register their products in Pakistan. The authorization letter is valid till 19-03-2026
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	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. 24632 : 31-08-2022

	Details of fee submitted	PKR 150,000/-: on 11-10-2021, Challan No 623767235857
	The proposed proprietary name / brand name	**Freefol MCT 1% Injection 20ml Vial (Propofol 10mg/ml)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Propofol…….200mg
	Pharmaceutical form of applied drug	White color Emulsion for injection Packed in vial.
	Pharmacotherapeutic Group of (API)	General Anesthetic properties (N01AX10)
	Reference to Finished product specifications	European pharmacopeia
	Proposed Pack size	20ml vial x10's
	Proposed unit price	As per brand leader
	The status in reference regulatory authorities	Propofol Lipuro 1% **(USFDA** Approved).
	For generic drugs (me-too status)	Propofol 1% MCT Fresenius Injection of Fresenius (Reg #099485)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Bachem SA, Succursale de Vionnaz, Route du Simplon 22, 1895, Vionnaz, Switzerland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25 °C /60 % RH for 60 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence performed against reference product i.e Fresofol MTC 1% Injection Lot No 16FC0249. All quality parameters as per official monograph were compared against Test product Lot No N001
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

	Container closure system of the drug product	USP type-I clear glass vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. Batch No 19034. 19048, 19062 The real time stability study data is conducted at 30 °C / 75% RH. The real time stability study data of 3 batches is for 24months. Batch No R015, R016, R017.
Decision: Registration Board decided to refer the case to Authority for seeking guidance upon priority consideration of the applied formulation.		

Case No.02; Deferred cases of form 5F.

30.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 17-01-2022 is provided.
	Evidence of approval of manufacturing facility	copy of Valid DML No. 000911 (Formulation) valid till 13-02-2025 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27912 Date: 03/10/2022
	Details of fee submitted	PKR 30000 dated: 28-07-2022 . SLIP No. 9108432875
	The proposed proprietary name / brand name	**Actogen 100ml Vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Paracetamol 10mg/ml solution for infusion
	Pharmaceutical form of applied drug	Solution for Infusion
	Pharmacotherapeutic Group of (API)	Anti-Pyretic
	Reference to Finished product specifications	Innovator Specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	**Brand Name:** Provas (10mg/ml) **Registration holder:** M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi. **Registration Number:** 050650
	Name and address of API manufacturer.	M/s Citi Pharma (Pvt) Ltd, 3 km, Head Balloki Road, Phool Nagar, Kasur. GMP Certificate No. 10444/2016-DRAP/2016

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 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	Pharmaceutical Equivalence have not been established/submitted with innovator Product, but with Provas Infusion of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of validation of analytical method (In-House) for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Citi Pharma (Pvt) Ltd, 3 km, Head Balloki Road, Phool Nagar, Kasur. GMP Certificate No. 10444/2016-DRAP/2016		
API Lot No.	**Not Provided**		
Description of Pack (Container closure system)	1's		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	11-2021	11-2021	11-2021

Date of Initiation	20-11-2021	20-11-2021	20-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not Submitted. • Firm has stated that Biogen is a new license section and no such data is submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sun Pharmaceutical Industries Limited, Industrial Area - 3 A.B. Road 455001 Madhya Pradesh , India DML No. 24/24/83 in form no. 25 & 28/15/83 in form no.28
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not required.**
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	**Not Submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Submitted.**

Evaluation by PEC :

1. Provide updated GMP certificate of API manufacturer M/s Citi Pharma Kasur as the submitted GMP certificated is dated 2016.
2. API manufacturer (M/s citi Pharma Kasur) has performed melting point test for identification of API but has set specifications different from those as mentioned in BP.
3. API manufacturer (M/s citi Pharma Kasur) has performed impurities testing as mentioned in BP but the acceptance criteria is kept at Not more than 1 % while the one mentioned in BP is max .2%
4. Provide the detailed analytical method with complete detail (method verification) along with test reports of API as performed by the Drug Product manufacturer.
5. The Manufacturing Protocol/Procedure for manufacture/Product Development (including sterility testing) are not submitted.
6. Batch detail along with BMR (including sterility testing) is not provided for manufacturing of Drug Product.
7. Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.
8. Submit microbial reports for the sterility testing of drug product along during stability studies.
9. Pharmaceutical Equivalence studies along with test reports results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted with innovator Product of Drug Product are not submitted.
10. Submit microbial reports for the sterility testing of drug product during stability studies.
11. Provide compatibility study protocol along with reports as the excipients being used are different from the ones mentioned/used in innovator Product (USFDA)
12. In chromatogram of stability studies, study on blank and respective chromatogram of blank is not submitted.
13. Compliance Record of HPLC software 21CFR & audit trail reports on product testing needs to be submitted.
14. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.

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

Updated reply

Sr. No	Observations	Reply	Remarks
9.	Provide updated GMP certificate of API manufacturer M/s Citi Pharma Kasur as the submitted GMP certificate is dated 2016.	Not provided	Later on GMP certificate based on inspection dated 17.12.2020 was provided.
10.	API manufacturer (M/s citi Pharma Kasur) has performed melting point test for identification of API but has set specifications different from those as mentioned in BP	The mentioned melting point specification range is as per BP.	Justified
11.	API manufacturer (M/s citi Pharma Kasur) has performed impurities testing as mentioned in BP but the acceptance criteria is kept at Not more than 1 % while the one mentioned in BP is max .2%	The mentioned impurities specification/ acceptance criteria is as per BP.	Justified
12.	Provide the detailed analytical method with complete detail (method verification) along with test reports of API as performed by the Drug Product manufacturer.	Detailed analytical method with method verification studies/ test reports of API are provided.	Complied
13.	The Manufacturing Protocol/Procedure for manufacture/Product Development (including sterility testing) are not submitted.	Not provided	Manufacturing Protocol/Procedure for manufacture/Product Development to be provided with details of sterilization mechanism (whether aseptic filling/membrane filtration/terminal sterilization)
14.	Batch detail along with BMR (including sterility testing) is not provided for manufacturing of Drug Product	Provided	Complied
15.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.	Not provided	Firm submitted that HPLC Instrument is not 21CFR Compliance we already submitted the logbook of HPLC .
16.	Submit microbial reports for the sterility testing of drug product along during stability studies.	Provided	Complied
17.	Pharmaceutical Equivalence studies along with test reports results of all the quality tests	Pharmaceutical Equivalence have been established against	Complied

	(mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted with innovator Product of Drug Product are not submitted.	established brand **Provas Infusion** by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi Batch No 148 G	
18.	Provide compatibility study protocol along with reports as the excipients being used are different from the ones mentioned/used in innovator Product (USFDA)	Excipients being used are same as used in innovator Product (USFDA)	Verified.
19.	In chromatogram of stability studies, study on blank and respective chromatogram of blank is not submitted.	Not provided	Later on firm submitted analytical study report of blank and respective chromatogram
20.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.	Provided	Complied

Decision: Deferred for submission of manufacturing procedure for applied product along with details of sterilisation procedure applied.

31.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 17-01-2022 is provided.
	Evidence of approval of manufacturing facility	copy of Valid DML No. 000911 (Formulation) valid till 13-02-2025 is provided along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28776 Date: 11/10/2022
	Details of fee submitted	PKR 30000 dated: 14-07-2022 . SLIP No. 9829497909
	The proposed proprietary name / brand name	Cilagen 250mg Injection IV (Powder for injection/infusion)

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem (as Monohydrate)---------250mg Cilastatin (as Sodium)---------250mg
	Pharmaceutical form of applied drug	Powder for solution for injection/infusion
	Pharmacotherapeutic Group of (API)	Anti-Biotics (Anti Bacterial)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO **Innovator Product (MHRA) :** Pack sizes: 1 x 250 mg vial 10 x 250 mg vial Not all pack sizes may be marketed.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	**Brand Name:** Cilapen 250mg Injection **Registration holder:** Bosh pharmaceuticals **Registration Number:** 048490
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Limited, Industrial Area - 3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^{o}C \pm 2^{o}C$ / 75% ± 5% RH for 6 months. The real time stability data is conducted at $30^{o}C \pm 2^{o}C$ / 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	Pharmaceutical Equivalence have been not been established/submitted.
	Analytical method validation/verification of product	Not Submitted.
STABILITY STUDY DATA		

Manufacturer of API	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019 valid till 02-10-2022		
API Lot No.	Imipenem Monohydrate & Cilastatin Sodium: API Lot No is AB06493		
Description of Pack (Container closure system)	As per SRO		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 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.	001	002	003
Batch Size	700 vials	700 vials	700 vials
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	04-12-2021	04-12-2021	04-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not Submitted. • Firm has stated that Biogen is a new license facility and no such data is submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India DML No. 24/24/83 in form no. 25 & 28/15/83 in form no.28
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**The invoice of relevant batch** AB06493 **used in Product Development is not provided.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not Submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Submitted.**

Evaluation by PEC:

1. Provide the analytical method with complete detail as the submitted documents contain missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.
2. Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer.
3. The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.
4. Batch detail along with BMR is not provided for manufacturing of Drug Product.
5. Documents for the procurement of API with approval from DRAP **of relevant batch** AB06493 **used in Product Development is not provided.**
6. Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.
7. Submit microbial reports for the sterility testing of drug product during stability studies.
8. Pharmaceutical Equivalence studies along with test reports are not submitted.

9. Provide supportive data i.e. attested respective documents like chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc.

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

Sr No	Observation	Reply	Remarks
1.	Provide the analytical method with complete detail as the submitted documents contain missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Substance manufacturer.
2.	Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Product manufacturer.
3.	The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.	Not provided	Not complied
4.	Batch detail along with BMR is not provided for manufacturing of Drug Product.	Provided	Complied
5.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 used in Product Development is not provided.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 provided Invoice No 7000041892 dated 12.10.2021	Complied
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.	Not provided	Firm submitted that HPLC Instrument is not 21CFR Compliance we already submitted the logbook of HPLC .
7.	Submit microbial reports for the sterility testing of drug product during stability studies	Provided	Complied
8.	Pharmaceutical Equivalence studies along with test reports are not submitted	Pharmaceutical Equivalence studies along with test reports are provided against **Tienam 500mg injection** by M/s OBS pharma Batch No 154 C	Complied

		Quality parameters compared were identification, LOD, Ph, constituted solution, uniformity of dosage unit, particulate matter, Assay, BET, Sterility	
9.	Provide supportive data i.e. attested respective documents like chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc.	Supportive data i.e. chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc. are provided	Complied

Decision: Deferred for following reasons:

- **The Manufacturing Protocol/Procedure for manufacture/Product Development to be submitted.**
- **Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.**

32.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences 8 km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of current GMP certificate dated 17-01-2022 is provided.
	Evidence of approval of manufacturing facility	copy of Valid DML No. 000911 (Formulation) valid till 13-02-2025 is provided along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28777 Date: 11/10/2022
	Details of fee submitted	PKR 30000 dated: 14-07-2022 . SLIP No. 63961987615
	The proposed proprietary name / brand name	Cilagen 500mg Injection IV (Powder for injection/infusion)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem (as Monohydrate)---------500mg Cilastatin (as Sodium)---------500mg
	Pharmaceutical form of applied drug	Powder for solution for injection/infusion
	Pharmacotherapeutic Group of (API)	Anti-Biotics (Anti Bacterial)
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	As per SRO **Innovator Product (MHRA) :**

		Pack sizes: 1 x 250 mg vial 10 x 250 mg vial Not all pack sizes may be marketed.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved** **(Primaxin Injection 500mg), Merck Inc USA.**
	For generic drugs (me-too status)	**Brand Name:** Cilapen 500mg Injection **Registration holder:** Bosh pharmaceuticals **Registration Number:** 048491
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 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	Pharmaceutical Equivalence have not been established/submitted.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA

Manufacturer of API	Sun Pharmaceutical Industries Limited, Industrial Area -3 A.B. Road 455001 Madhya Pradesh , India GMP Certificate No. V/WHOGMP/Rev/Sun-17/2019 valid till 02-10-2022
API Lot No.	Imipenem Monohydrate & Cilastatin Sodium: API Lot No is AB06493
Description of Pack (Container closure system)	**As per SRO**
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 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.	004	005	006
Batch Size	700 vials	700 vials	700 vials
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	04-12-2021	04-12-2021	04-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not Submitted. • Firm has stated that Biogen is a new license facility and no such data is submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sun Pharmaceutical Industries Limited, Industrial Area - 3 A.B. Road 455001 Madhya Pradesh , India DML No. 24/24/83 in form no. 25 & 28/15/83 in form no.28
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**The invoice of relevant batch** AB06493 **used in Product Development is not provided.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not Submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Submitted.**

Evaluation by PEC:

1. Pack size of Drug Product is not submitted.
2. Provide the analytical method with complete detail as the submitted documents contain, missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.
3. Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer.
4. The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.
5. Batch detail along with BMR is not provided for manufacturing of Drug Product.
6. Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.
7. Documents for the procurement of API with approval from DRAP **of relevant batch** AB06493 **used in Product Development is not provided.**
8. Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.
9. Submit microbial reports for the sterility testing of drug product along during stability studies.
10. Pharmaceutical Equivalence studies along with test reports of Drug Product with innovator Product are not submitted.
11. Provide supportive data i.e. attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
12. Detail of equipment/machinery needs to be submitted.
13. The chromatograms of HPLC submitted along with stability data sheets do not specify the analyte (whether standard , sample etc).

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

Sr No	Observation	Reply	Remarks
1.	Pack size of Drug Product is not submitted.	Not provided	Later on firm provided proposed Pack size of Drug Product as 1's As per SRO.
2.	Provide the analytical method with complete detail as the submitted documents contain missing/cutting along with test reports of API as performed by the Drug Substance manufacturer.	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Substance manufacturer.
3.	Provide the analytical method with complete detail along with test reports of API as performed by the Drug Product manufacturer	Not provided	Later on firm submitted detailed analytical method of Drug Substance from Drug Product manufacturer.
4.	The Manufacturing Protocol/Procedure for manufacture/Product Development are not submitted.	Not provided	Not complied
5.	Batch detail along with BMR is not provided for manufacturing of Drug Product.	Provided	Complied
6.	Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.	Not provided	Not complied
7.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 used in Product Development is not provided.	Documents for the procurement of API with approval from DRAP of relevant batch AB06493 provided Invoice No 7000041892 dated 12.10.2021	Complied
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not Provided.	Not provided	Firm submitted that HPLC Instrument is not 21CFR Compliance we already submitted the logbook of HPLC .
9.	Submit microbial reports for the sterility testing of drug product during stability studies	Provided	Complied
10.	Pharmaceutical Equivalence studies along with test reports are not submitted	Pharmaceutical Equivalence studies along with test reports are provided against **Tienam 500mg injection**	Complied

		by M/s OBS pharma Batch No 154 C Quality parameters compared were identification, LOD, Ph, constituted solution, uniformity of dosage unit, particulate matter, Assay, BET, Sterility	
11.	Provide supportive data i.e. attested respective documents like chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc.	Supportive data i.e. chromatograms specifying whether of standard or sample etc, Raw data sheets, COA, summary data sheets etc. are provided	Complied
12.	Detail of equipment/machinery needs to be submitted.	Complied	Complied
13.	The chromatograms of HPLC submitted along with stability data sheets do not specify the analyte (whether standard , sample etc).	Provided	Complied

Decision: Deferred for following reasons:

- **The Manufacturing Protocol/Procedure for manufacture/Product Development to be submitted.**
- **Stability data along with data sheets of three batches of API as performed by the API manufacturer needs to be submitted.**

Agenda of Evaluator PEC-XV

Case No. 01 OUT OF QUEUE CONSIDERATION OF APPLICATION OF REGISTRATION OF DRUGS OF MANUFACTURES HAVING GMP CERTIFICATE FROM PIC/S MEMBER NRAS:

DRAP in its 157th meeting of Authority held on 20th January,2023 decided that, "*For pharmaceutical manufacturers who acquire GMP certification from any PIC/S member country, the Authority as an incentive approved the out-of-queue consideration of registration of 05 molecules, on CTD per calendar year during the validity of the PIC/S country' issued GMP certificate to boost the pharmaceutical exports".*

Accordingly, *M*/s Dynatis Pakistan (Pvt.) Ltd., Lahore had requested for consideration of following registration applications out of queue, since the firm has acquired GMP Certificate from PIC/S member country. Two molecules of the firm under instant priority have been considered by the Board in its 324th meeting. Third molecule of the firm is submitted for consideration of the Board.

33.	Name, address of Applicant / Marketing Authorization Holder	M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sundar Industrial Estate, Lahore, Pakistan.
	Name, address of Manufacturing site.	M/s Dynatis Pakistan (Pvt.) Ltd.

		Plot No. 710, 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. 5897 dated 02/03/2023
	Details of fee submitted	PKR 75,000/-: dated 28/02/2023
	The proposed proprietary name / brand name	**Versi Tablet 2.5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vericiguat…….……..….2.5mg
	Pharmaceutical form of applied drug	White colored round biconvex film coated tablets plain from both sides.
	Pharmacotherapeutic Group of (API)	Cardiac therapy, other vasodilator, use in cardiac disease.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 98's and 100's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Verquvo Tablet 2.5mg by Bayer AG, Leverkusen, Germany., USFDA Approved.
	For generic drugs (me-too status)	Not applicable, since applied product is not registered yet in Pakistan.
	GMP status of the Finished product manufacturer	GMP certificate based on evaluation conducted on 26-03-2021.
	Name and address of API manufacturer.	**Vericiguat:** Changzhou Pharmaceutical Factory. **Address:** No.518, Laodong East Road, Changzhou, Jiangsu Province 213018, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and process controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Vericiguat:**

		Real time: 30°C ± 2°C / 65% ± 5%RH for 12 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (PIVCG-2110001, PIVCG-2112001, PIVCG-2112002).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Verquvo Tablet 2.5mg by Bayer AG, Leverkusen, Germany., Inc., USFDA Approved by performing quality tests (Assay, Dissolution, Average weight). CDP has been performed against the same brand that is Verquvo Tablet 2.5mg by Bayer AG, Leverkusen, Germany, Inc., USFDA Approved, in HCl buffer pH 1.2, Acetate Buffer pH 4.5, Phosphate buffer pH 6.8 and Release medium (0.01M HCl). The values are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity & range, precision (repeatability & intermediate precision), accuracy (recovery), specificity, robustness, solution stability, system suitability, LOD and LOQ.

STABILITY STUDY DATA

Manufacturer of API	**Vericiguat:** Changzhou Pharmaceutical Factory. **Address:** No.518, Laodong East Road, Changzhou, Jiangsu Province 213018, China.		
API Lot No.	Vericiguat: SYVCG-210601		
Description of Pack (Container closure system)	The product is filled in Alu-Alu blister. Each blister contains seven tablets and each unit carton contains two blisters (2 x 7's tablets/pack).		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 and 6 (Months) Real Time: 0, 3, 6 and 9 (Months)		
Batch No.	TEA-002	TEA-003	-
Batch Size	5000 Tablets	5000 Tablets	-
Manufacturing Date	12-2021	12-2021	-
Date of Initiation	15-12-2021	24-12-2021	-
No. of Batches	02		

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Vericiguat:** GMP certificate issued by Jiangsu Changzhou Drug Administration valid till 15/11/2024.

15.	Documents for the procurement of API with approval from DRAP (in case of import).	**Vericiguat:** Vericiguat invoice # CY121287, DRAP# 14394/2021 DRAP signed on: 24/09/2021.
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	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.1**	Please provide the detail related to the polymorphic form of drug substance, since according to the review report of innovator brand five polymorphic forms were identified during development, along with several solvated and hydrated forms and amorphous material.	Firm replied that as per innovator review literature and DMF there are five polymorphic forms along with solvated and hydrated forms. Whereas, different polymorphic forms do not differ in dissolution behavior and drug substance manufacturer synthesize polymorphic Form-I which is the most thermodynamically stable.
2.	**3.2. S.4.1**	Justify for not including the test of palladium and particle size test (laser diffraction) in the specification of drug substance ,since these test are included in the specification of drug substance of innovator product.	Firm replied that "we developed the product as per FDA. Test for palladium is not mentioned in FDA chemistry review for this product. Moreover, particle size test by drug substance manufacturer is added in the specifications".
3.	**3.2.P.2.2.1**	Justify for using polysorbate in the dissolution medium of pH 4.5 and pH 6.8 for dissolution profiling of applied product with reference product and submit the reply along with supporting international reference.	Firm replied that "According to BCS classification, vericiguat belong to class II (low soluble & high permeable). According to USP chapter 1092; the aqueous solution (acidic or buffer solution) may contain a percentage of surfactant to enhance solubility of drug substance. Ideally the amount of surfactant added is sufficient to achieve the sink condition in the desired volume of dissolution medium, so we can use surfactant according to USP chapter 1092".
4.	**3.2.P.5.2**	Clarify the pH of dissolution medium, the submitted analytical procedure did not specify the pH of dissolution medium.	Firm replied that "We have used pH 2.0 for dissolution medium as per innovator approved dissolution specifications. Revised Finished Drug Product testing method along with Innovator reference is 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.**		
34.	Name, address of Applicant / Marketing Authorization Holder	M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, Sundar Industrial Estate, Lahore, Pakistan.
	Name, address of Manufacturing site.	M/s Dynatis Pakistan (Pvt.) Ltd. Plot No. 710, 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. 5896 02/03/2023
	Details of fee submitted	PKR 75,000/-: dated 28/02/2023
	The proposed proprietary name / brand name	**Versi Tablet 5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Vericiguat……..……..……5mg
	Pharmaceutical form of applied drug	Round biconvex red film coated tablet plain on both sides.
	Pharmacotherapeutic Group of (API)	Cardiac therapy, other vasodilator, use in cardiac disease.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 98's and 100's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Verquvo Tablet 5mg by Bayer AG, Leverkusen, Germany., USFDA Approved.
	For generic drugs (me-too status)	Not applicable, since applied product is not registered yet in Pakistan.
	GMP status of the Finished product manufacturer	GMP certificate based on evaluation conducted on 26-03-2021.
	Name and address of API manufacturer.	**Vericiguat:** Changzhou Pharmaceutical Factory. **Address:** No.518, Laodong East Road, Changzhou, Jiangsu Province 213018, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data

		related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and process controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Vericiguat:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PIVCG-2110001, PIVCG-2112001, PIVCG-2112002).
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product that is Verquvo Tablet 5mg by Bayer AG, Leverkusen, Germany., Inc., USFDA Approved by performing quality tests (Assay, Dissolution, Average weight). CDP has been performed against the same brand that is Verquvo Tablet 5mg by Bayer AG, Leverkusen, Germany, Inc., USFDA Approved, in HCl buffer pH 1.2, Acetate Buffer pH 4.5, Phosphate buffer pH 6.8 and Release medium (0.01M HCl). The values are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity & range, precision (repeatability & intermediate precision), accuracy (recovery), specificity, robustness, solution stability, system suitability, LOD and LOQ.

STABILITY STUDY DATA

Manufacturer of API	**Vericiguat:** Changzhou Pharmaceutical Factory. **Address:** No.518, Laodong East Road, Changzhou, Jiangsu Province 213018, China.		
API Lot No.	Vericiguat: SYVCG-210601		
Description of Pack (Container closure system)	The product is filled in Alu-Alu blister. Each blister contains seven tablets and each unit carton contains two blisters (2 x 7's tablets/pack).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 and 6 (Months) Real Time: 0, 3, 6 and 9 (Months)		
Batch No.	TEB-001	TEB-002	-
Batch Size	5000 Tablets	5000 Tablets	-
Manufacturing Date	12-2021	12-2021	-

Date of Initiation	17-12-2021	24-12-2021	-
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Vericiguat:** GMP certificate issued by Jiangsu Changzhou Drug Administration valid till 15/11/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Vericiguat:** Vericiguat invoice # CY121287, DRAP# 14394/2021 DRAP signed on: 24/09/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	**3.2.S.1**	Please provide the detail related to the polymorphic form of drug substance, since according to the review report of innovator brand five polymorphic forms were identified during development, along with several solvated and hydrated forms and amorphous material.	Firm replied that as per innovator review literature and DMF there are five polymorphic forms along with solvated and hydrated forms. Whereas, different polymorphic forms do not differ in dissolution behavior and drug substance manufacturer synthesize polymorphic Form-I which is the most thermodynamically stable.
2.	**3.2. S.4.1**	Justify for not including the test of palladium and particle size test (laser diffraction) in the specification of drug substance ,since these test are included in the specification of drug substance of innovator product.	Firm replied that "we developed the product as per FDA. Test for palladium is not mentioned in FDA chemistry review for this product. Moreover, particle size test by drug substance manufacturer is added in the specifications".
3.	**3.2.P.2.2.1**	Justify for using polysorbate in the dissolution medium of pH 4.5 and pH 6.8 for dissolution profiling of applied product with reference product and submit the reply along with supporting international reference.	Firm replied that "According to BCS classification, vericiguat belong to class II (low soluble & high permeable). According to USP chapter 1092; the aqueous solution (acidic or buffer solution) may contain a percentage of surfactant to enhance solubility of drug substance. Ideally the amount of surfactant added is sufficient to achieve the sink condition in the desired volume of dissolution medium, so we can use surfactant according to USP chapter 1092".
4.	**3.2.P.5.2**	Clarify the pH of dissolution medium, the submitted analytical procedure did not specify the pH of dissolution medium.	Firm replied that "We have used pH 2.0 for dissolution medium as per innovator approved dissolution specifications. Revised Finished Drug Product testing method along with Innovator reference is 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.

Case No. 02 EXPORT FACILITATION CASE:

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR-I (EFD) dated 28th Feb,2023 "M/s Ferozsons Laboratories Limited, have achieved benchmark OF USD 2108059.57 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 1 products applications submitted by the firm."		
35.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30784 dated 31-10-2022
	Details of fee submitted	PKR 75,000/-: dated 12/09/2022
	The proposed proprietary name / brand name	APRIVA TABLETS 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablets contains: Apremilast ….30mg
	Pharmaceutical form of applied drug	Brown Round, 9.5mm biconvex film coated tablet with "*f*" on one side and plain on other side
	Pharmacotherapeutic Group of (API)	Antineoplastic and Immunomodulating Agents
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	7's, 10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OTEZLA TABLETS BY Amgen Inc
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP certificate No. F. 11-6/2021-DRAP-65 granted on 25/08/2021 Valid up to 10-08-2023. Tablet (General) section approved vide letter No. F.3-14/2004-Lic, dated: 08-04-2015 is submitted.
	Name and address of API manufacturer.	Glenmark Life Sciences Limited Address: Plot No. Z-103-I, SEZ Phase II, Dahej, Taluka Vagra, District Bharuch, Gujarat – 392 130, 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)	Apremilast is In-house, the firm submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for single/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 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AMTab-007, AMTab-008, AMTab-009)
	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 Otezla Tablets by Amgen Inc (USA), by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Otezla Tablets by Amgen Inc (USA). The dissolution profile has shown release less than 85 % in all three Buffer pH 1.2, Phosphate Buffer pH 6.8 and Acetate Buffer pH 4.5 in 15 minutes. So, calculation of similarity factor f_2 is calculated which is "66" for Buffer pH 1.2, "63" for Phosphate Buffer pH 6.8 and "75" for Acetate Buffer pH 4.5 which is more than 50. Hence dissolution profile of both Apriva tablets and Otezla Tablet found similar.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Glenmark Life Sciences Limited Address: Plot No. Z-103-I, SEZ Phase II, Dahej, Taluka Vagra, District Bharuch, Gujarat – 392 130, India.
API Lot No.	82190049
Description of Pack (Container closure system)	Apremilast Tablets 30mg: Alu-PVDC blister of 10 Tablets
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	AMTab-007	AMTab-008	AMTab-009.
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	19-09-2020	19-09-2020	19-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21082834 issued by Food and Drug Controls Administration, Block No.8, 1st floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujrat State, India valid till 06/08/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form-6, No.00198/2019-DRAP (Ps)/817 dated 26/02/2019, DRAP acknowledgment for receiving of Apremilast, Commercial invoice, packing list, Form-3 & Form-7 and Goods declarations is submitted wherein the permission to import Apremilast for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
3.	**3.2.P.5.2**	Justify for not adopting the updated dissolution condition of Apremilast tablet as specified in the dissolution database of USFDA.	Firm replied that the product is also tested by adopting updated dissolution conditions of Apremilast tablet as specified in the dissolution database of USFDA and found complies, result for the same along with chromatogram is submitted.

Decision: Approved.

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

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

Agenda of Evaluator PEC-X

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

a. New DML

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 Dry Powder-I	27	10

Oral Dry Powder-I

34.	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	Acavon 98% WSP
	Composition	Each 100gm Powder Contains: Metrifonate (Trichlorophon)…98gm
	Diary No. Date of R& I & fee	Dy.No 6826 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Cholinesterase inhibitor/ insecticide
	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	Trinoor-98 Oral Powder of M/s Kohinoor Industries, Sahiwal. (Reg. No. 081306)
	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 including its legal status in regional and global regulatory authorities.	
35.	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	Acavon 96% WSP
	Composition	Each 100gm Powder Contains: Metrifonate (Trichlorophon)…96gm
	Diary No. Date of R& I & fee	Dy.No 6827 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Cholinesterase inhibitor/ insecticide
	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	Nawagan Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 053922)
	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 including its legal status in regional and global regulatory authorities..	
36.	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	Parapex-C WSP
	Composition	Each 100gm Powder Contains: **Paracetamol**…20gm

		Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm
	Diary No. Date of R& I & fee	Dy.No 6821 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Analgesic /Vitamins
	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	Para Ce Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063812)
	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	
37.	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-Aspro-C WSP
	Composition	Each 100gm Powder Contains: **Vitamin C**…20gm **Aspirin**…6.7gm
	Diary No. Date of R& I & fee	Dy.No 6803 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Salicylate/Vitamins
	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	B.G Aspro-C Water Soluble Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No.080146)
	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	
38.	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	Tylofos WSP
	Composition	Each 100gm Powder Contains: Tylosin Tartrate…5gm Calcium Fosfomycin…20gm Fructose 1,6 diphosphate…18gm Sodium Phosphate…15gm Magnesium Phosphate…10gm
	Diary No. Date of R& I & fee	Dy.No 6801 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	Rekco Tyfox Oral Powder of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No. 111368)
	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 formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

39.	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	Fosfotyl Forte WSP
	Composition	Each 100gm Powder Contains: Tylosin Tartrate…10gm Calcium Fosfomycin…20gm Fructose…18gm Sodium Phosphate…15gm
	Diary No. Date of R& I & fee	Dy. No 6800 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	Fosomax Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat. (Reg. No. 063808) **Could not be confirmed in the applied combination**
	GMP status	New DML
	Remarks of the Evaluator [X]	• The firm has now revised the formulation as mentioned below: Each 100gm Powder Contains: Tylosin Tartrate…10gm Calcium Fosfomycin…20gm Fructose 1,6 diphosphate…18gm Sodium Phosphate…15gm Magnesium Sulphate….10gm
	Decision: Approved with following label claim: **Each 100gm Powder Contains:** **Tylosin as Tartrate…10gm** **Calcium Fosfomycin…20gm** **Fructose 1,6 diphosphate…18gm** **Sodium Phosphate…15gm** **Magnesium Sulphate….10gm** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation 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 Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Aclinco 4.4% Oral Powder
	Composition	Each 100gm Powder Contains: Lincomycin as HCl…4.4gm
	Diary No. Date of R& I & fee	Dy.No 6794 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Lincorox Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No.111506)
	GMP status	New DML
	Remarks of the Evaluator [X]	• The firm has now revised the formulation as mentioned below: Each 100gm Powder Contains: Lincomycin HCl…4.4gm
	Decision: Approved with following label claim: **Each 100gm Powder Contains:**	

	Lincomycin HCl…4.4gm **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
41.	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	Aclinco 11% Oral Powder
	Composition	Each 1000gm Powder Contains: Lincomycin as HCl…110gm
	Diary No. Date of R& I & fee	Dy.No 6795 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Linco-GP Oral Powder of M/s Jfrin Pharmaceuticals, Karachi. (Reg. No. 043246)
	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 formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
42.	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	Aclinco 40% Oral Powder
	Composition	Each 1000gm Powder Contains: Lincomycin as HCl…400gm
	Diary No. Date of R& I & fee	Dy.No 6796 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Lincomycin-40s Oral Powder of M/s Orient Traders International, Karachi. (Reg. No. 093614)
	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 formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
43.	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	Aclinco 1.1% Oral Powder
	Composition	Each 100gm Powder Contains: Lincomycin as HCl…1.1gm
	Diary No. Date of R& I & fee	Dy.No 6797 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled

	Me-too status	Lincorox Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No.111505)
	GMP status	New DML
	Remarks of the Evaluator [X]	• The firm has now revised the formulation as mentioned below: Each 100gm Powder Contains: Lincomycin HCl…1.1gm
	Decision: Approved with following label claim: **Each 100gm Powder Contains:** **Lincomycin as HCl…1.1gm** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
44.	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	Acmetylo 20% WSP
	Composition	Each 1000gm Powder Contains: Tylosin Phosphate…200gm
	Diary No. Date of R& I & fee	Dy. No 6819 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	Tyloman-20% Premix of M/s Manhattan Pharma Karachi (Reg. No. 021402)
	GMP status	New DML
	Remarks of the Evaluator [X]	• The firm has now revised the formulation as mentioned below: Each 1000gm Powder Contains: Tylosin Phosphate eq. to Tylosin base…200gm
	Decision: Approved with following label claim: **Each 1000gm Powder Contains:** **Tylosin as Phosphate…200gm** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
45.	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	Acmetylo 10% WSP
	Composition	Each 1000gm Powder Contains: Tylosin Phosphate…100gm
	Diary No. Date of R& I & fee	Dy.No 6818 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	Super Tylan Feed Premix Powder of M/s Farm Aid Group Pakistan, Hattar. (Reg. No. 029636)
	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 formulation 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 Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmecol 55 Oral Powder
	Composition	Each 100gm Powder Contains: Colistin Sulphate…550 MIU
	Diary No. Date of R& I & fee	Dy.No 6811 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	Colsin 550 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke. (Reg. No. 112303)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
47.	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 50 Oral Powder
	Composition	Each 1gm Powder Contains: Colistin Sulphate…5,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 6812 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	Colicid Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113525)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
48.	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 460 Oral Powder
	Composition	Each 100gm Powder Contains: Colistin Sulphate…46,000,000,0 IU
	Diary No. Date of R& I & fee	Dy.No 6813 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	Stin Rold 46% Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd.Bhimber, AJK. (Reg. No. 109116)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
49.	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 52 Oral Powder
	Composition	Each 100gm Powder Contains: Colistin Sulphate…520,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 6814 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	Stin Rold 52% Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd.Bhimber, AJK. (Reg. No. 109117)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
50.	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 48 Oral Powder
	Composition	Each 1gm Powder Contains: Colistin Sulphate…480,000,0 IU
	Diary No. Date of R& I & fee	Dy.No 6815 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	Coli Skill-48 Powder of M/s Bioskils Pharmaceuticals, Sadhoke, District Gujranwala. (Reg. No. 113508)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
51.	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 40 Oral Powder
	Composition	Each 100gm Powder Contains: Colistin Sulphate…400 MIU
	Diary No. Date of R& I & fee	Dy.No 6816 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	Hascoli-400 Water Soluble Powder of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 113388)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
52.	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 60 Oral Powder
	Composition	Each 1gm Powder Contains: Colistin Sulphate…600,000,0 IU

	Diary No. Date of R& I & fee	Dy.No 6817 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	Colivetz Oral Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 079296)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
53.	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	Highneo 60% Oral Powder
	Composition	Each 1000gm Powder Contains: Neomycin Sulphate…600gm
	Diary No. Date of R& I & fee	Dy.No 6807 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	Neoritis-60 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke. (Reg. No. 111419)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
54.	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	Highneo 28.59 %
	Composition	Each 1gm Powder Contains: Neomycin Sulphate…28.59%
	Diary No. Date of R& I & fee	Dy.No 6808 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	Neomax Water Soluble Powder of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 073907)
	GMP status	New DML
	Remarks of the Evaluator [X]	The firm has now revised the formulation as mentioned below: Each 1gm Powder Contains: Neomycin Sulphate…28.59%
	Decision: Approved with following label claim: **Each 1gm Powder Contains:** **Neomycin …28.59%** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
55.	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	Highneo 72% Oral Powder

	Composition	Each 1000gm Powder Contains: Neomycin Sulphate…720gm
	Diary No. Date of R& I & fee	Dy.No 6809 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	Neomycin 720 Water Soluble Powder of M/s Westmont Pharmaceuticals Industry Rawalpindi. (Reg. No. 053945)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
56.	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	Highneo 70% Oral Powder
	Composition	Each 1000gm Powder Contains: Neomycin Sulphate…700gm
	Diary No. Date of R& I & fee	Dy.No 6810 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	Neomycin 70% Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075694)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
57.	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 25% WSP
	Composition	Each 100gm Powder Contains: Oxytetracycline HCl…25gm
	Diary No. Date of R& I & fee	Dy.No 6838 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Oxymix – 250 Water Soluble Powder of M/s Cherished Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058806)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
58.	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 20% WSP
	Composition	Each 100gm Powder Contains: Oxytetracycline HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 6837 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial

	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Eter Oxytetracycline-20 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 109838)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
59.	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 50% WSP
	Composition	Each 100gm Powder Contains: Oxytetracycline HCl…50gm
	Diary No. Date of R& I & fee	Dy.No 6836 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Nobitet 50% Powder of M/s Noble Pharma, Industrial Area, Mirpur Azad Kashmir (Reg. No. 063643)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	
60.	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 95% WSP
	Composition	Each 100gm Powder Contains: Oxytetracycline HCl…95gm
	Diary No. Date of R& I & fee	Dy.No 6835 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Oxybar Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore.(Reg. No. 079818)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved	

Agenda of Evaluator PEC-III

Cases of New Section:

M/s Don Valley has submitted copy of a letter dated 05-11-2019 for grant of additional section. The letter specifies Tablet II (General) Section.		
36.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Don Valley Pharmaceuticals (Pvt.) Ltd 31-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	The firm has submitted copy of inspection report dated 13-02-2020 confirming good compliance to GMP.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 23-08-2019 issued on the basis of inspection dated 06-08-2019 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2254: 24-01-2023
	Details of fee submitted	PKR 30,000/-: 18-01-2023
	The proposed proprietary name / brand name	**EMPADON 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…25mg
	Pharmaceutical form of applied drug	Pink colored, round biconvex coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xelglu Tablet by Hilton
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for 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 Jardiance Tablet Firm has submitted results of CDP for their product against Jardiance Tablet.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China.		
API Lot No.	L-E-20211130-D06-E06-02		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-IY-22-01	T-IY-22-02	T-IY-22-03
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	27-05-2022	27-05-2022	27-05-2022
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)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate specifying import of 0.25Kg Empagliflozin. The clearance certificate is issued on 20-04-2022.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 for Nirmatrelvir drug substance 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."

- Justify the verification studies of analytical procedure of drug substance from drug product manufacturer, since the drug product manufacturer has adopted a different analytical method in terms of column size, column temperature, standard solution and sample solution.
- The result of sample 3 at 80% concentration in repeatability test gives 60% result. Justify how you passed this test since the test does not qualify the acceptance criteria.
- The HPLC chromatograms of verification studies depict that the date acquired for all analysis of linearity and range is 1-May -22: 10:07AM which is not practically possible. Justify how multiple HPLC chromatograms having different peak areas were acquired on same date and same time.
- The analytical method provided in verification studies specifies 20µL injection volume while all chromatograms specify 10µL injection volume.
- HPLC chromatogram for sample 1 of 120% specify the height as 544.73 while the scale of chromatogram is till 480. Justify how the height could be 544 while the chromatogram is below 480 as per vertifcal scale.
- Three chromatograms submitted after sample 3 of 140% concentration with sample name 0, date acquired 1-May-22 10:07AM and date processed 1-May-22 12:59 PM show retention time 2.59 with exactly same peak as in other chromtaograms but the area and height is 0. Clarify how the peak area and height is 0 with the clear peak in the print.
- Justify why the qualitative composition of your formulation is different from the innovator's product.
- Provide information regarding batch number, expiry date and manufacturer of the innovator product against which pharmaceutical equivalence and CDP studies were conducted.
- Justify the adaptation of dissolution parameters, since they are different from that recommended by the innovator's product in terms of RPM. You have selected 100RPM while the innovator's product has specified 75 RPM.
- Justify the dissolution acceptance criteria NLT 75%(Q) in 45 minutes, while the innovator's product acceptance criteria is NLT (Q) in 15 minutes. Justify your dissolution criteria in the light of decision of Registration Board taken in its 293rd meeting which specifies that "*For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator / reference product with reference to dissolution specification will not be acceptable"*
- Justify why content uniformity test is not included in the drug product specifications.
- Analytical method of drug product specifies that concentration of standard and sample preparation is 0.025mg/ml while you have performed verification studies keeping the target concentration 0.1mg/ml. Justify how these studies represent your analytical method.
- USFDA review documents reveals that the innovator's drug product shows more than 85% release in 15 minutes, while your stability results indicate that the product disintegration time is greater than 15 minutes. Justify how your product could be considered equivalent to the innovator's product.
- Submit valid GMP certificate / Drug manufacturing license of API manufacturer issued by relevant regulatory authority of country of origin, since the submitted GMP is not issued by relevant regulatory authority of China.
- The submitted audit trail report shows different time of acquisition of HPLC chromatograms than that mentioned on the relevant chromatograms. Clarification is required in this regard.
- Submit BMR of three executed stability batches.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Agenda of Evaluator PEC-XXIII

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

a. New cases

37.	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	ZETI 10mg tablet
	Composition	Each film coated tablet contains: Ezetimibe ……..….10mg
	Diary No. Date of R& I & fee	Dy No. 14602 dated 07-03-2019 Fee paid PKR 20,000/- dated 07-03-2019 vide Deposit Slip No. 0792392 dated 06-03-2019
	Pharmacological Group	Other lipid modifying agents ATC Code C10AX09
	Type of Form	Form 5

	Finished Product Specification	Firm has not stated the product specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zetia 10mg tablet Company: Organon USFDA Approved
	Me-too status	Zitamibe 10mg Tablet Mass Pharma
	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 in specifications to Pharmacopoeial Specs (USP) along with PKR 7500/- fee is required • Evidence of product approved in reference regulatory authority is of uncoated tablets, applied product is film coated. Approval of film coated tablet in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or change in formulation from film coated to uncoated tablet as available in reference regulatory authority is required, along with prescribed fee.
	Decision: Deferred for following: • **Evidence of approval of applied formulation as film coated tablet dosage form, in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or 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.** • **Submission of reference for pharmacopoeial specifications along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**	
38.	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	MCAM 15mg tablet
	Composition	Each tablet contains: Meloxicam…… 15mg
	Diary No. Date of R& I & fee	Dy No. 16736 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792367 dated 06-03-2019.
	Pharmacological Group	Oxicams ATC Code M01AC06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mobic 15mg tablet USFDA Approved
	Me-too status	Melor Tablet by Sami
	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.	
39.	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	MCAM 7.5mg tablet
	Composition	Each tablet contains: Meloxicam ……..….. 7.5mg
	Diary No. Date of R& I & fee	Dy No. 16735 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792368 dated 06-03-2019.
	Pharmacological Group	Oxicams

		ATC Code M01AC06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mobic 7.5mg tablet USFDA Approved
	Me-too status	Melor Tablet by Sami
	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.	
40.	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	TIZAN 2mg tablet
	Composition	Each tablet contains: Tizanidine Hydrochloride equivalent to Tizanidine ….....2mg
	Diary No. Date of R& I & fee	Dy No. 16737 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792365 dated 06-03-2019.
	Pharmacological Group	Muscle relaxants, centrally acting agents ATC Code M03BX02
	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	Tizafed 2mg Tablet Fedro Pharmaceutical Labs 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.	
41.	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	TIZAN 4mg tablet
	Composition	Each tablet contains: Tizanidine Hydrochloride equivalent to Tizanidine….. 4mg
	Diary No. Date of R& I & fee	Dy No. 16738 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792363 dated 06-03-2019.
	Pharmacological Group	Muscle relaxants, centrally acting agents ATC Code M03BX02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zanaflex 4mg tablet USFDA Approved
	Me-too status	Tizafed 4 mg Tablet Fedro Pharmaceutical Labs 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.	
42.	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	ATELOL 50mg tablet
	Composition	Each film coated tablet contains: Atenolol ……..…50mg
	Diary No. Date of R& I & fee	Dy No. 14604 dated 07-03-2019 Fee paid PKR 20,000/- dated 07-03-2019 vide Deposit Slip No. 0792394 dated 06-03-2019.
	Pharmacological Group	Selective Beta blocker
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Totamol 50mg tablet MHRA Approved
	Me-too status	Atokyt 100mg Tablet Hi-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.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
43.	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	ATELOL 100mg tablet
	Composition	Each film coated tablet contains: Atenolol ……..100mg
	Diary No. Date of R& I & fee	Dy No. 14603 dated 07-03-2019 Fee paid PKR 20,000/- dated 07-03-2019 vide Deposit Slip No. 0792393 dated 06-03-2019.
	Pharmacological Group	Selective Beta blocker
	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	Atokyt 100mg Tablet Hi-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.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
44.	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 8mg tablet
	Composition	Each film coated tablet contains: Candesartan Cilexetil ……..…… 8mg
	Diary No. Date of R& I & fee	Dy No. 14606 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792396 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 8 mg Tablets - PL 35084/0002-9; MHRA Approved.
	Me-too status	Cansaar 8mg Tablet 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 (MHRA) 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 PKR 7500/- fee is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation as film coated tablet dosage form, in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or 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.**	
45.	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	AVENTEC 16mg/12.5mg tablet
	Composition	Each film coated tablet contains: Candesartan Cilexetil…….... 16mg Hydrochlorothiazide…… 12.5mg
	Diary No. Date of R& I & fee	Dy. No. 14607 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792398 dated 06-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code C09DA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atacand HCT; USFDA Approved.
	Me-too status	CST-H 16mg/12.5mg Tablet Pharmasol (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. • Applied product is film coated tablet. USFDA approved product is uncoated tablets. Approval of film coated tablet in reference regulatory authority or change of formulation from film coated to uncoated tablet along with PKR 7500/- fee is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation as film coated tablet dosage form, in reference regulatory authorities/agencies (which were adopted by Registration Board in its 275th meeting) or 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.**	
46.	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	PIVASTA 2mg tablet
	Composition	Each film coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin ……..….. 2mg
	Diary No. Date of R& I & fee	Dy No. 14578 dated 07-03-2019 Fee paid PKR 20,000 vide Deposit Slip No. 0789181 dated 07-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code C10AA08
	Type of Form	Form 5

	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Livalo 2mg tablet USFDA Approved
	Me-too status	Pinstatin 2mg Tablet Moringa 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.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
47.	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	PIVASTA 1mg tablet
	Composition	Each film coated tablet contains: Pitavastatin Calcium equivalent to Pitavastatin…. 1mg
	Diary No. Date of R& I & fee	Dy No. 14577 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789180 dated 07-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code C10AA08
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Livalo 1mg tablet USFDA Approved
	Me-too status	Pinstatin 1mg Tablet Moringa 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.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
48.	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	ALGORIC tablet 100mg
	Composition	Each tablet contains: Allopurinol 100mg
	Diary No. Date of R& I & fee	Dy No. 16731 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792372 dated 06-03-2019.
	Pharmacological Group	Anti gout preparations ATC Code M04AA01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyloric 100 mg Tablets MHRA Approved
	Me-too status	Zyloric 100mg Tablet GlaxoSmithKline Pakistan 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.	
49.	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	ALGORIC tablet 300mg
	Composition	Each tablet contains: Allopurinol ……..…….300mg
	Diary No. Date of R& I & fee	Dy No. 16732 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792371 dated 06-03-2019.
	Pharmacological Group	Anti gout preparations ATC Code M04AA01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyloric 300 mg Tablets MHRA Approved
	Me-too status	Zyloric 300mg Tablet GlaxoSmithKline Pakistan 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.	
50.	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	FINATE capsule 67mg
	Composition	Each hard gel capsule contains: Fenofibrate ……67 mg
	Diary No. Date of R& I & fee	Dy. No. 14570 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789173 dated 07-03-2019.
	Pharmacological Group	Lipid modifying agents ATC Code C10AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipantil Micro 67 mg, capsule MHRA Approved
	Me-too status	Valofibren 67mg Capsule Valor 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.
	Decision: Deferred for submission of latest GMP inspection report conducted within last three years.	
51.	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	FINATE capsule 200mg
	Composition	Each hard gel capsule contains: Fenofibrate ……..…….200mg
	Diary No. Date of R& I & fee	Dy No. 14569 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789172 dated 07-03-2019.
	Pharmacological Group	Lipid modifying agents ATC Code C10AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipantil Micro 200 mg, capsule MHRA Approved
	Me-too status	Trifibe Capsules 200mg Pulse Pharmaceuticals (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.	
52.	**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-H tablet 20/12.5mg
	Composition	Each film coated tablet contains: Amlodipine …….……20mg Hydrochlorthiazide ……12.5mg
	Diary No. Date of R& I & fee	Dy No. 14611 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0792248 dated 06-03-2019.
	Pharmacological Group	Calcium channel blockers and diuretics ATC Code C08GA02
	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.	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 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 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.** • **Provision of finished product specifications,**	
53.	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 20/10mg
	Composition	Each film coated tablet contains: Amlodipine …….……20mg Olmesartan Medoxomil ……..…..5mg
	Diary No. Date of R& I & fee	Dy No. 14589 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0789192 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.	Approved by US FDA
	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. • Product monograph is available in USP. • Strength of applied product on cover letter, fee challan and other points in application form is 20/10mg. However, in the label claim strength mentioned is 20/5mg. Clarification is required along with correction of label claim and submission of prescribed 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: • **Revision of label claim for the complete salt form of Amlodipine as per innovator product along with prescribed fee as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.** • **Change in specifications to Pharmacopoeial Specs (USP).** • **Clarification regarding applied strength since covering letter and applied label claim mentions different strengths.** • **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.**	
54.	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	U-TAC 6.4mg tablet
	Composition	Each film coated tablet contains: Glyceryl trinitrate…… 6.4mg
	Diary No. Date of R& I & fee	Dy No. 14581 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789184 dated 07-03-2019
	Pharmacological Group	Vasodilators used in cardiac diseases ATC Code C01DA02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications, as claimed by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found in film coating
	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. • Firm has applied for film coated tablet. In reference regulatory authority (MHRA), approved product is prolonged release oral tablet. Change in dosage form from film-coated tablet to prolonged release tablet along with prescribed fee (PKR 30,000) is required. • It is not clear whether applied product is oral or sub lingual tablet. • 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
55.	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	U-TAC 2.6mg tablet
	Composition	Each film coated tablet contains:

		Glyceryl trinitrate…….….. 2.6mg
	Diary No. Date of R& I & fee	Dy No. 14580 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0789183 dated 07-03-2019
	Pharmacological Group	Vasodilators used in cardiac diseases ATC Code C01DA02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications, as claimed by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found in film coating
	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. • Firm has applied for film coated tablet. In reference regulatory authority (MHRA), approved product is prolonged release oral tablet. Change in dosage form from film-coated tablet to prolonged release along with prescribed fee (PKR 30,000) is required. • It is not clear whether applied product is oral or sub lingual tablet • 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
56.	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	WARIN 5mg tablet
	Composition	Each film coated tablet contains: Warfarin ……. 5mg
	Diary No. Date of R& I & fee	Dy No. 14610 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792247 dated 06-03-2019
	Pharmacological Group	Antithrombotic agents ATC Code B01AA03
	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.	Not found in film coating
	Me-too status	Coagurin (Warfarin Sodium) 5mg Tablets Atco Laboratories Limited (Available in salt form)
	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 specifications are not provided. Warfarin sodium tablets are available in USP. • Firm has applied for film coated tablet whereas in reference regulatory authority (MHRA), the pharmaceutical form is uncoated tablet. Change of formulation is required along with submission of prescribed fee. • In applied product, the API is Warfarin whereas API in product approved in reference regulatory authority is as Warfarin Sodium. Firm may be advised to change the composition to salt form in accordance with product approved in reference regulatory authority,

		along with prescribed fee for pre-registration variation as follows: Each tablet contains: Warfarin Sodium …..5mg
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
57.	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	Pri-AM tablet 8/10mg
	Composition	Each film coated modified release tablet contains: 8mg Perindopril terbutylamine (equivalent to 6.68mg Perindopril) Amlodipine (as besylate)……10mg
	Diary No. Date of R& I & fee	Dy No. 16742 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792380 dated 06-03-2019
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC Code C09BB04
	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.	Not confirmed
	Me-too status	Not found in applied formulation
	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 film coated modified release tablet 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
58.	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	Pri-AM tablet 8/5mg
	Composition	Each film coated modified release tablet contains: 8mg Perindopril terbutylamine (equivalent to 6.68mg Perindopril) Amlodipine (as besylate)……5mg
	Diary No. Date of R& I & fee	Dy No. 16741 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792379 dated 06-03-2019
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC Code C09BB04
	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.	Not confirmed
	Me-too status	Not found in applied formulation
	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 film coated modified release tablet 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
59.	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	Pri-AM tablet 4/5mg
	Composition	Each film coated modified release tablet contains: 4mg Perindopril terbutylamine (equivalent to 3.34mg Perindopril) Amlodipine (as besylate)……5mg
	Diary No. Date of R& I & fee	Dy No. 16739 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792375 dated 06-03-2019
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC Code C09BB04
	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.	Not confirmed
	Me-too status	Not found in applied formulation
	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 film coated modified release tablet 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
60.	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	Pri-AM tablet 4/10mg
	Composition	Each film coated modified release tablet contains: 4mg Perindopril terbutylamine (equivalent to 3.34mg Perindopril) Amlodipine (as besylate)……10mg
	Diary No. Date of R& I & fee	Dy No. 16740 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792378 dated 06-03-2019
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC Code C09BB04
	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.	Not confirmed
	Me-too status	Not found in applied formulation
	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 film coated modified release tablet 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: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	
61.	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	QPin tablet 50mg
	Composition	Each film coated tablet contains: Quetiapine Fumarate equivalent to Quetiapine…..50mg
	Diary No. Date of R& I & fee	Dy No. 16733 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 0792377 dated 06-03-2019
	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.	Seroquel 50mg film coated tablet USFDA Approved
	Me-too status	Not found in applied formulation
	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 applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within three months.	

Registration-I Section

Case No.1. Request for Change in Registration Status of Products from M/s The Searle Company Limited Karachi to M/s Searle Pakistan Limited (Formerly OBS Pakistan Private Limited Karachi)

M/s. Searle Pakistan Limited (Formerly OBS Pakistan Pvt Ltd.), C-14, Manghopir Road, S.I.T.E, Karachi (DML No.000012) has requested for change in registration of below mentioned products from M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016) to their name.

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of registration letter and last renewal status.
ii. Copy of GMP certificate of M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi issued on 15-02-22 on the basis of inspection conducted on 08-10-2021.
iii. Copy of DML (000012) of M/s. Searle Pakistan Limited, C-14, Manghopir Road, SITE, Karachi, renewed w.e.f. 31-03-2020. Copy of letter for change of title / management issued by CLB on 23rd November, 2021.
iv. Copy of panel inspection report of M/s Searle Pakistan for GMP Certification dated 08-10-2021 confirming "Tablet (General) Section on the GMP Certification" Copy of approved sections by Central Licensing Board of M/s. Searle Pakistan Limited (Formely M/s OBS Pakistan Pvt. Ltd.) C-14 Manghopir Road, S.I.T.E Karachi confirming "Tablet (general)" section.
v. NOC from M/s. The Searle Company Ltd; Karachi for transfer of Co-Olesta 40mg/12.5mg Tablets and Co-Olesta 20mg/12.5mg Tablets in the name of M/s. Searle Pakistan Limited (Formerly OBS Pakistan Pvt Ltd.), C-14, Manghopir Road, S.I.T.E, Karachi issued on 28-10-2022

vi. Relevant undertakings & commitments.

The cases were referred to Pharmaceutical Evaluation Cell / QMS for scrutinization/evaluation. Detail of submitted documents along-with remarks of evaluator have been mentioned as under:

Evaluator: Mr. Asadullah (DD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
4.	058023	Co-Olesta 40mg/12.5mg Tablets Each tablet contains: - Olmesartan Medoxomil…..…40mg Hydrochlorthiazide 12.5mg (Manufacturer's Specification)	Initial Reg. Date: **01-08-2009** Change of Manufacturer Name: **19-08-2016** Last Renewal Submission date: **30-06-2021 with fee of Rs.15000/-**
	Name, address of Applicant / Marketing Authorization Holder		**M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700,,Sindh, Pakistan**
	Name, address of Manufacturing site.		M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi-75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt Ltd, C-14, Manghopir Road, S.I.T.E , Karachi- 75700, issued on 15-02-2022 based on inspection conducted on 08.10.2021.
	Evidence of approval of manufacturing facility		Applicant has provided copy of letter dated 26-10-2020 of renewal of DML mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.35295 (R&I) dated 06-12-2022
	Details of fee submitted		**For transfer of registration:** PKR 30,000/- DS# 938228899 dated 29-11-2022
	The proposed proprietary name / brand name		Co-Olesta 40 mg/12.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Olmesartan Medoxomil 40mg Hydrochlorothiazide 12.5mg
	Pharmaceutical form of applied drug		Blue round concave film coated tablet shaped with

		break-line on one side and plain from other side.
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker + Diuretic, Anti-hypertensive
	Reference to Finished product specifications	As per innovator's Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Benicar HCT 40mg/12.5mg Tablet, (FDA Approved)
	For generic drugs (me-too status)	Co-Baritec 40mg/12.5mg Tablet, Barret Hodgson Pakistan (Pvt) Ltd. (Reg#067519)
	Name and address of API manufacturer.	**Olmesartan:** Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India **Hydrochlorothiazide:** CTX Life Sciences Pvt Ltd, Gujrat State, India
	1.5.11-Proposed Label	Submitted
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Olmesartan medoxomil (DS) physical properties, solubilities, polymorphism, other general properties, manufacturing site, Characterization elucidation using FTIR, impurities profiling of organic / in-process known impurities as per USP monograph and analysis of 03 batches data (NMT 0.10% and total impurities NMT 1.30%), other impurities like heavy metals and residual solvents were also controlled in DS specifications. USP based DS specifications were followed by DP manufacturer. Analytical procedures for DS were verified against USP methods by DP manufacturer. DS lot procured is analyzed. Working standards, container closure and stability studies summaries of 03 batches of Olmesartan medoxomil was provided under Zone IV-b. Information related to Hydrochlorothiazide was summarized for its chemical structure, physical properties, solubility, polymorphism (Form-I is produced by CTX Life sciences), manufacturing site, brief manufacturing process was provided. DS characterization was performed using various spectrometric techniques. Specification was assigned as per USP monograph and analytical method was developed and verified. Reference standard from USP lot J0F070 was used to prepare working standard. LDPE bags packed in HDPE drum was used as Container closure system and stability studies were performed at zone iv-b conditions. Similarly, information summaries for drug product (Co-Olesta) including its description, composition, choice of excipients, compatibility, pharmaceutical development, manufacturing process development, pharmaceutical equivalence, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, DP specification based on Inhouse method, analytical procedure and its validation, batch analysis, reference/working standard, container closure system and stability studies has been

		provided.
	Module-III Drug Substance:	Firm has submitted data for both drug substances. **For Olmesartan medoxomil,** information related to its nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurity profiling, heavy metals and residual solvents were also identified and analysed in 03 DS batches which reveals within acceptable limits. USP Specifications were assigned except for residual solvents, bulk density and particle size which were tested as per in house method. Analytical method was developed and validated for assay, related substances and residual solvents by Glenmark pharma, India. Searle Pakistan ltd also developed analytical method verification protocol and provided verification report. Batch analysis of 3 batches were provided with their Certificate of analysis. DS lot procured by Searle Pakistan was also analysed against specifications based on USP and compared with CoA of DS manufacturer. Preparation of working standards and its CoA was provided. Container closure system, specification and test methods for packing materials, and stability studies with study protocol was provided. For Hydrochlorothiazide: information related to nomenclature, physical properties, manufacturing and laboratory sites details, brief on manufacturing process, starting materials were provided. Critical manufacturing steps and intermediate, manufacturing process development and validation were not disclosed. Structure elucidations studies were performed using various spectroscopy techniques. Impurities, related substance and was identified. Specification was assigned as per USP monograph by both DS and DP manufacturers. Analytical method was developed and verified based on USP method by DS manufacturer followed by DP manufacturer. Batch analysis of 3 batches were provided which complied the specifications. DS lot procured by Searle Pakistan Ltd was analysed and compared with CoA of DS manufacturer Justification for specification is provided. Working standard was prepared against USP reference standard and its CoA was provided. Reference standards for related substances were inhouse developed. Information related to Container Closure system, its CoAs and safety certificates were provided. Stability study protocol and result sheets were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Olmesartan Medoxomil:** 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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the **long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 36 months**. DS was packed in a double polyethylene bag (inner clear and outer black opaque) and placed in a

fibre board / HDPE Drum. The DS remained within specified limits as tested on defined intervals.

Hydrochlorothiazide:

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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the **long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 72 months**. DS was packed in LDPE bags which is closed with twist tie and inserted in a second LDPE bag which is also closed with a twist tie. The bag is finally placed in a well closed fibre Drum. The DS remained within specified limits as tested on defined intervals.

Module-III Drug Product:

Firm has submitted data of drug product including its physical appearance, composition, choice f excipients, compatibility studies, manufacturing process and process control, formulation development, manufacturing process development and validation protocol, critical quality attributes, process flow and summary, excipients testing methods based on pharmacopeial methods, pharmaceutical equivalence, specifications based on inhouse methods, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, reference standard for DS, container closure system, and stability studies were provided.

Pharmaceutical Equivalence and Comparative Dissolution Profile

Pharmaceutical equivalence was performed against Olmetec Plus 40mg/12.5mg Tablets manufactured by Daiichi Sankyo, Turkey, which shows comparable results within specified limits.

The comparative dissolution profile was performed for Co-Olesta 40mg/12.5mg Tablet (Batch# 024DT01, Exp Date:04-2022) against the Olmetec Plus 40mg/12.5mg (Batch #18N348, Exp Date:09-2023) manufactured by Daiichi sankyo, Turkey. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45min. Calculation of value is as under:

Mediums	**Time interval**	**HCZ**		**Olmesartan**	
		Test	**Ref**	**Test**	**Ref**
Acidic buffer (pH 1.2)	05 min	96	88	94	88
	10 min	96	98	93	96
	15 min	96	97	90	92
	20 min	97	98	88	90
	30 min	98	98	87	88
	45 min	96	99	83	85
	f1 = 3 f2= 71			f1 = 3 f2= 74	
Acetate buffer (pH 4.5)*	05 min	93	82	6	6
	10 min	95	98	8	8
	15 min	95	98	8	8
	20 min	95	100	8	9
	30 min	98	99	8	8
	45 min	97	100	8	8
	f1=5 f2=63			f1=2 f2=98	
Phosphate Buffer (pH 6.8)	05 min	93	89	56	41
	10 min	92	96	60	53
	15 min	93	97	58	53

		<table><tr><td></td><td>20 min</td><td>93</td><td>96</td><td>54</td><td>49</td></tr><tr><td></td><td>30 min</td><td>92</td><td>95</td><td>50</td><td>48</td></tr><tr><td></td><td>45 min</td><td>89</td><td>92</td><td>45</td><td>45</td></tr><tr><td></td><td colspan="3">f1=4 f2=72</td><td colspan="2">f1=12 f2=56</td></tr></table> * The solubility of Olmesartan is pH dependent, and it is practically insoluble at pH 4.0.
	Analytical method validation/verification of product	Firm has claimed inhouse (as per innovator's) specifications for which report of validation of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided which meets the acceptance criteria for verification.

STABILITY STUDY DATA

Manufacturer of API	**Olmesartan:** Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India **Hydrochlorothiazide:** CTX Life Sciences Pvt Ltd, Gujrat State, India		
API Lot No.	**Olmesartan:** 83191080 / 0098NPD **Hydrochlorothiazide:** 20HZ00044 / 0084NPD		
Description of Pack (Container closure system)	Alu/PVC blister in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months (Continue for 24 months) Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,18.24 (Months)		
Batch No.	024DT01	024DT02	024DT03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	04-2020	04-2020	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)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Olmesartan:** Firm has submitted copy of GMP certificate issued by Food and Drug Administration (Maharashtra State) Pune, India , dated 25-01-2022. (Valid up to 24-01-2023). **Hydrochlorothiazide:** Firm has submitted copy of GMP Certificate issued by Food and Drug Administrating (Gujrat, India) on 30-05-2022 (valid upto 29-05-2025)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Olmesartan API was purchased from Glenmark Life Sciences, Pune, India, invoice dated 31-12-2019, cleared 27-01-2020 from DRAP, Karachi. Hydrochlorothiazide API was purchased from CTX Life Sciences, India invoice dated 24-12-2019, cleared 10-02-2020 from DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 of stability batches.
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.

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
5.	058022	Co-Olesta 20mg/12.5mg Tablets Each tablet contains: - Olmesartan Medoxomil…..…20mg Hydrochlorthiazide 12.5mg (Manufacturer's Specification)	Initial Reg. Date: **01-08-2009** Change of Manufacturer Name: **19-08-2016** Last Renewal Submission Date: **30-06-2021 with fee of Rs.15000/-**
	Name, address of Applicant / Marketing Authorization Holder		**M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700,,Sindh, Pakistan**
	Name, address of Manufacturing site.		M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi-75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt Ltd, C-14, Manghopir Road, S.I.T.E , Karachi- 75700, issued on 15-02-2022 based on inspection conducted on 08.10.2021.
	Evidence of approval of manufacturing facility		Applicant has provided copy of letter dated 26-10-2020 of renewal of DML mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.35294 (R&I) dated 06-12-2022
	Details of fee submitted		**For transfer of registration:** PKR 30,000/- DS# 73955131364 dated 29-11-2022
	The proposed proprietary name / brand name		Co-Olesta 20 mg/12.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Olmesartan Medoxomil 20mg Hydrochlorothiazide 12.5mg

	Pharmaceutical form of applied drug	white round concave shaped film coated tablet shaped with break-line on one side and plain from other side.
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker + Diuretic, Anti-hypertensive
	Reference to Finished product specifications	As per innovator's Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Benicar HCT 20mg/12.5mg Tablet, (FDA Approved)
	For generic drugs (me-too status)	Co-Baritec 20mg/12.5mg Tablet, Barret Hodgson Pakistan (Pvt) Ltd. (Reg#067251)
	Name and address of API manufacturer.	**Olmesartan:** Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India **Hydrochlorothiazide:** CTX Life Sciences Pvt Ltd, Gujrat State, India
	1.5.11-Proposed Label	Submitted
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Olmesartan medoxomil (DS) physical properties, solubilities, polymorphism, other general properties, manufacturing site, Characterization elucidation using FTIR, impurities profiling of organic / in-process known impurities as per USP monograph and analysis of 03 batches data (NMT 0.10% and total impurities NMT 1.30%), other impurities like heavy metals and residual solvents were also controlled in DS specifications. USP based DS specifications were followed by DP manufacturer. Analytical procedures for DS were verified against USP methods by DP manufacturer. DS lot procured is analyzed. Working standards, container closure and stability studies summaries of 03 batches of Olmesartan medoxomil was provided under Zone IV-b. Information related to Hydrochlorothiazide was summarized for its chemical structure, physical properties, solubility, polymorphism (Form-I is produced by CTX Life sciences), manufacturing site, brief manufacturing process was provided. DS characterization was performed using various spectrometric techniques. Specification was assigned as per USP monograph and analytical method was developed and verified. Reference standard from USP lot J0F070 was used to prepare working standard. LDPE bags packed in HDPE drum was used as Container closure system and stability studies were performed at zone iv-b conditions. Similarly, information summaries for drug product (Co-Olesta) including its description, composition, choice of excipients, compatibility, pharmaceutical development, manufacturing process development, pharmaceutical equivalence, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, DP specification

		based on Inhouse method, analytical procedure and its validation, batch analysis, reference/working standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for both drug substances. **For Olmesartan medoxomil,** information related to its nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurity profiling, heavy metals and residual solvents were also identified and analysed in 03 DS batches which reveals within acceptable limits. USP Specifications were assigned except for residual solvents, bulk density and particle size which were tested as per in house method. Analytical method was developed and validated for assay, related substances and residual solvents by Glenmark pharma, India. Searle Pakistan ltd also developed analytical method verification protocol and provided verification report. Batch analysis of 3 batches were provided with their Certificate of analysis. DS lot procured by Searle Pakistan was also analysed against specifications based on USP and compared with CoA of DS manufacturer. Preparation of working standards and its CoA was provided. Container closure system, specification and test methods for packing materials, and stability studies with study protocol was provided. For Hydrochlorothiazide: information related to nomenclature, physical properties, manufacturing and laboratory sites details, brief on manufacturing process, starting materials were provided. Critical manufacturing steps and intermediate, manufacturing process development and validation were not disclosed. Structure elucidations studies were performed using various spectroscopy techniques. Impurities, related substance and was identified. Specification was assigned as per USP monograph by both DS and DP manufacturers. Analytical method was developed and verified based on USP method by DS manufacturer followed by DP manufacturer. Batch analysis of 3 batches were provided which complied the specifications. DS lot procured by Searle Pakistan Ltd was analysed and compared with CoA of DS manufacturer Justification for specification is provided. Working standard was prepared against USP reference standard and its CoA was provided. Reference standards for related substances were inhouse developed. Information related to Container Closure system, its CoAs and safety certificates were provided. Stability study protocol and result sheets were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Olmesartan Medoxomil:** 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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the **long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 36**

		months. DS was packed in a double polyethylene bag (inner clear and outer black opaque) and placed in a fibre board / HDPE Drum. The DS remained within specified limits as tested on defined intervals. **Hydrochlorothiazide:** 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 was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the **long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 72 months**. DS was packed in LDPE bags which is closed with twist tie and inserted in a second LDPE bag which is also closed with a twist tie. The bag is finally placed in a well closed fibre Drum. The DS remained within specified limits as tested on defined intervals.
	Module-III Drug Product:	Firm has submitted data of drug product including its physical appearance, composition, choice f excipients, compatibility studies, manufacturing process and process control, formulation development, manufacturing process development and validation protocol, critical quality attributes, process flow and summary, excipients testing methods based on pharmacopeial methods, pharmaceutical equivalence, specifications based on inhouse methods, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, reference standard for DS, container closure system, and stability studies were provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Olmetec Plus 20mg/12.5mg Tablets manufactured by Daiichi Sankyo, Turkey, which shows comparable results within specified limits. The comparative dissolution profile was performed for Co-Olesta 20mg/12.5mg Tablet (Batch# 023DT03, Exp Date:04-2022) against the Olmetec Plus 20mg/12.5mg (Batch #20F971, Exp Date:05-2023) manufactured by Daiichi sankyo, Turkey. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45min. Calculation of value is as under:

Mediums	**Time interval**	**HCZ**		**Olmesartan**	
		Test	**Ref**	**Test**	**Ref**
Acidic buffer (pH 1.2)	05 min	88	97	84	87
	10 min	93	100	87	86
	15 min	94	97	84	83
	20 min	93	99	82	82
	30 min	94	95	80	77
	45 min	95	96	79	76
	f1 = 5 f2= 63			f1 = 2 f2= 81	
Acetate buffer (pH 4.5)*	05 min	95	77	10	10
	10 min	97	100	13	12
	15 min	95	100	14	12
	20 min	100	103	16	14
	30 min	101	102	16	14
	45 min	104	106	17	14

<table>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td colspan="3">f1=5
f2=55</td><td colspan="2">f1=13
f2=85</td></tr>
<tr><td rowspan="8">Phosphate Buffer (pH 6.8)</td><td>05 min</td><td>88</td><td>93</td><td>63</td><td>60</td></tr>
<tr><td>10 min</td><td>93</td><td>96</td><td>71</td><td>66</td></tr>
<tr><td>15 min</td><td>96</td><td>96</td><td>69</td><td>61</td></tr>
<tr><td>20 min</td><td>96</td><td>99</td><td>62</td><td>58</td></tr>
<tr><td>30 min</td><td>99</td><td>98</td><td>55</td><td>53</td></tr>
<tr><td>45 min</td><td>98</td><td>98</td><td>50</td><td>47</td></tr>
<tr><td colspan="3">f1=2
f2=77</td><td colspan="2">f1=7
f2=66</td></tr>
</table>
* The solubility of Olmesartan is pH dependent, and it is practically insoluble at pH 4.0.
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed inhouse (as per innovator's) specifications for which report of validation of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided which meets the acceptance criteria for verification.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
<tr><td>Manufacturer of API</td><td colspan="2">Olmesartan: Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India
Hydrochlorothiazide: CTX Life Sciences Pvt Ltd, Gujrat State, India</td></tr>
<tr><td>API Lot No.</td><td colspan="2">Olmesartan: 83191080 / 0098NPD
Hydrochlorothiazide: 20HZ00044 / 0084NPD</td></tr>
<tr><td>Description of Pack (Container closure system)</td><td colspan="2">Alu/PVC blister in unit carton</td></tr>
<tr><td>Stability Storage Condition</td><td colspan="2">Real time: 30˚C ± 2˚C / 75% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH</td></tr>
<tr><td>Time Period</td><td colspan="2">Real time: 24 months
Accelerated: 6 months</td></tr>
<tr><td>Frequency</td><td colspan="2">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9,12,18.24 (Months)</td></tr>
<tr><td>Batch No.</td><td>023DT01</td><td>023DT02</td><td>023DT03</td></tr>
<tr><td>Batch Size</td><td>3000 Tablets</td><td>3000 Tablets</td><td>3000 Tablets</td></tr>
<tr><td>Manufacturing Date</td><td>04-2020</td><td>04-2020</td><td>04-2020</td></tr>
<tr><td>Date of Initiation</td><td>10-04-2020</td><td>10-04-2020</td><td>10-04-2020</td></tr>
<tr><td>No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="4">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="2">-</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="2">Olmesartan: Firm has submitted copy of GMP certificate issued by Food and Drug Administration (Maharashtra State) Pune, India , dated 25-01-2022. (Valid up to 24-01-2023).
Hydrochlorothiazide: Firm has submitted copy of GMP Certificate issued by Food and Drug Administrating (Gujrat, India) on 30-05-2022 (valid upto 29-05-2025)</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="2">Olmesartan API was purchased from Glenmark Life Sciences, Pune, India, invoice dated 31-12-2019, cleared 27-01-2020 from DRAP, Karachi. Hydrochlorothiazide API was purchased from</td></tr>
</table>

		CTX Life Sciences, India invoice dated 24-12-2019, cleared 10-02-2020 from DRAP Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 of stability batches.
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: Registration Board decided as under:

ii. Cancelled registration of following products from the name of M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016) subject to submission of request for withdrawal/ cancellation of registration of below mentioned products:

S. No.	Reg. No.	Product Name & Composition
4.	**058023**	**Co-Olesta 40mg/12.5mg Tablets** **Each tablet contains: -** **Olmesartan Medoxomil……..…..…40mg** **Hydrochlorthiazide……12.5mg** **(Manufacturer's Specification)**
5.	**058022**	**Co-Olesta 20mg/12.5mg Tablets** **Each tablet contains: -** **Olmesartan Medoxomil……...…20mg** **Hydrochlorthiazide…….12.5mg** **(Manufacturer's Specifications)**

iii. Approved registration of following products in the name of M/s Searle Pakistan Limited (Formerly M/s OBS Pakistan Pvt. Ltd.) C-14, S.I.T.E, Karachi (DML No.000012) and given the same brand name on the basis of NOC submitted by M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016).

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

d. Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
iv.	**Co-Olesta 40 mg/12.5mg Tablet** **Each film coated tablet contains:** **Olmesartan Medoxomil …….40mg** **Hydrochlorothiazide ……12.5mg** **(As per *Innovator's Specifications)**
v.	**Co-Olesta 20 mg/12.5mg Tablet** **Each film coated tablet contains:** **Olmesartan Medoxomil ……20mg** **Hydrochlorothiazide ……..12.5mg** **(As per *Innovator's Specifications)**

iv. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.2. Request for Change in Registration Status of Rolac 100mg Capsules from M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to M/s Sami Pharmaceuticals Pvt Ltd., F-140/A, S.I.T.E, Karachi (DML#000938).

M/s. Sami Pharmaceuticals Pvt Ltd. Karachi has requested to change the manufacturing site for their product Rolac 100mg Capsules (Reg. No 024491) from M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi (DML#000938).

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of DML of M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi (DML#000938) issued on 13-09-2021.
ii. Copy of approval letter (dated 13-09-2021) for issuance of DML (No.000938; by way of formulation) confirming "Spansules (General)".
iii. NOC from M/s. Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to transfer product, issued on 12-12-2022
iv. Relevant undertakings & commitments.

The cases were referred to Pharmaceutical Evaluation Cell / QMS for evaluation. Detail of submitted documents and remarks of evaluators have been mentioned as under:

Evaluator: Mr. Asadullah (DD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	024491	Rolac 100mg Capsules Each capsule contains: - Itraconazole……100 mg (BP Specification) (Pellets are manufactured at own facility as per approval letter dated 30-09-2003)	Initial Reg. Date: **14-03-2002** Change of FPP Specification: **19-04-2021** Renewal of Registration submitted on: **01-02-2022 with fee of Rs.15000/-**
	Name, address of Applicant / Marketing Authorization Holder		M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi
	Name, address of Manufacturing site.		**M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi (DML#000938)**
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		New License
	Evidence of approval of manufacturing facility		DML issuance covering letter dated 13-09-2021 confirming Spansules (General) as formulation 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.38186 (R&I) dated 28-12-2022
	Details of fee submitted		**For transfer of registration:** PKR 30,000/- DS# 7229163943 deposited on 26-10-2022
	The proposed proprietary name / brand name		Rolac 100mg Capsules

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Coated pellets of Iitraconazole MS equivalent to Iitraconazole 100 mg (BP Specification)
	Pharmaceutical form of applied drug	White to off white slight yellowish coloured pellets filled in hard Gelatin capsule Size No. 0 light Brown Opaque Cap with Rolac® printed on it and off white opaque body with company logo printed 3 times.
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	4's
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Sporanox 100mg Capsules, Janseen Pharma FDA (NDA 020083)
	For generic drugs (me-too status)	Icon 100mg Capsules, manufactured by Ferozsons laboratories (Reg# 050392)
	Name and address of API manufacturer.	Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road, SITE, Karachi
	1.5.11-Proposed Label	Same as already registered
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Monograph of Iitraconazole (DS) and capsule (FPP) is available in USP and BP. Firm has summarized information of Iitraconazole (DS) for its nomenclature, structure, physical properties, solubility and other general properties. The DS is Iitraconazole pellets was manufactured by Sami Pharma using API from Hetro Drugs Limited. Pellets manufacturer is a certified and is responsible for all steps of manufacturing, packing and quality testing. Characterization elucidation studies was conducted using IR, UV, NMR and mass spectrum. Potential impurities related to API was not identified. DS manufacturers followed in-house specification and accordingly analytical methods were developed and verified. DS batch was analyzed by DP manufacturer and compare against the CoA of DS manufacturer. Working standards, container closure and stability studies summaries of 03 batches were provided under Zone IV-b. Similarly, information summaries for drug product related to its description, composition, formulation development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against reference product were provided. Development of manufacturing process and in-process controls, batch formula, DP specification based on BP specification, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided. BMR of three stability batches were also provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubility, Character elucidation using spectroscopy IR and NMR. DS specifications were based on the in-house method and accordingly analytical method were developed and its verification studies were performed. DP manufacturer

<table>
<tr><td></td><td></td><td>also performed analytical analysis and method verification of itraconazole 22% pellets. Certificate of analysis of DS lot, batch analysis, reference/working standard and its CoA, container closure system, its specification and test methods for packing materials were provided. stability studies sheets were also provided.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance accelerated and 3 batches at real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for months. DS was packed in a transparent polyethylene bags placed in dark blue / black polyethylene bags in HDPE drum. The DS, remained stable and within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report. Pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of BP monograph and its verification studies were performed, batch analysis, reference standard, container closure system with specification and analysis reports were provided. Stability studies were performed for 3 batches.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Sporanox 100mg Capsule manufactured by Aspin Pharma Pakistan which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (PL-003) against the Sporanox 100mg Capsule (Batch A0953). Comparison was performed in 0.5% sodium lauryl sulphate in water using 12 samples for 60 minutes (BP monograph). Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="7"></td><td rowspan="7">0.5% sodium lauryl sulphate</td><td>10 min</td><td>12.45 %</td><td>12.03 %</td></tr>
<tr><td>15 min</td><td>39.38%</td><td>38.83%</td></tr>
<tr><td>30 min</td><td>90.35%</td><td>91.97%</td></tr>
<tr><td>45 min</td><td>102.44%</td><td>103.13 %</td></tr>
<tr><td>60 min</td><td>106.12%</td><td>106.57%</td></tr>
<tr><td colspan="3">F2=93.88</td></tr>
</table></td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed BP specifications for which report of analytical method verification for the drug product has been provided.</td></tr>
</table>

STABILITY STUDY DATA

Manufacturer of API	Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road, SITE, Karachi (DML # 000907)
API Lot No.	004T
Description of Pack (Container closure system)	Alu-Alu blister pack (10s).
Stability	Real time: 30˚C ± 2˚C / 65% ± 5%RH

Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 9 months (Continue for 24 month) Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	PL001	PL002	PL003
Batch Size	10,000 Capsules	10,000 Capsules	10,000 Capsules
Manufacturing Date	11-2021	12-2021	12-2021
Date of Initiation	12-2021	12-2021	12-2021
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 DRAP Karachi.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API was procured from Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road, SITE, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted 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 of stability batches.
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: **Registration Board decided as under:** M/s. Sami Pharmaceuticals Pvt Ltd. Karachi has requested to change the manufacturing site for their product Rolac 100mg Capsules (Reg. No 024491) from M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi (DML#000938)

i. **Cancelled registration of following products from the name of** M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) **subject to submission of request for withdrawal/ cancellation of registration of below mentioned products:**

S. No.	Reg. No.	Product Name & Composition
1.	**024491**	**Rolac 100mg Capsules** **Each capsule contains: -** **Itraconazole……100mg** **(BP Specification)**

ii. **Approved registration of following products in the name of M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi (DML#000938) and the same brands were given on the basis of NOC from M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072)**
   a) **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
   b) **Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.**

c) Before issuance of registration letter, the applicant shall submit comparative dissolution studies performed against the innovator's/ reference product in line with the guidance published vide minutes of 293rd meeting of Registration Board. [*Ref. Dissolution Profile Comparisons Through Model Independent Approach Using Similarity Factor; Page No. 43-44*]

S. No.	Product Name & Composition
i.	**Rolac 100mg Capsules** **Each capsule contains:** **Coated pellets of Itraconazole MS equivalent to Itraconazole 100 mg (BP Specification)** **Source of Pellets:** **Sami Pharmaceuticals (Pvt) Ltd, F-95, Off Hub River Road, SITE, Karachi (DML # 000907)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.03. Request for Change in Registration Status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro Along-with End to End Local Manufacturing.

Registration Board in its 323rd meeting held on 06th-08th December16th-17th May, 2022 considered the request of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro for change in registration status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name as per following details:

Detail of Previous Proceedings:

M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro initially applied for change in registration status from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name along-with end to end local manufacturing (Dy.No.33338/R&I dated 21-12-2021). However, the firm vide their letter No.REF/DRAP/Reg-003/0322 received dated10-03-2022 (Dy.No.6669) revised their request by informing that there is no change in manufacturing site (abroad) and repacking site (local). The case was considered by the Registration Board in its 317th meeting (held on 16th-17th May, 2022) and decided as under:

Decision of M-317:

Registration Board deferred the case for submission of updated approval status of the applied formulation along-with safety and efficacy profile in reference regulatory authorities adopted by the Board in its 275th meeting. Moreover, the Board further advised to submit valid and legalized CoPP of the product as existing has been expired.

In line with the above-mentioned decision of Registration Board, following information has been collected regarding risk-benefit profile of Paracetamol MR Tablet and regulatory steps taken by different reference regulatory authorities in the best interest of patients.

[Reference: Application to amend the Poisons Standard - Modified Release Paracetamol (tga.gov.au) accessed dated 04-11-2022]:

Paracetamol Modified Release Tablet:

Paracetamol MR tablets are constructed in two layers, an IR layer (31%) and a SR layer (69%) that gradually releases paracetamol over a period of 8 hours at normal doses.

The highest recommended dose of paracetamol for adults is 1.3 g and the maximum daily dose is 4 g (i.e., 2 tablets 3 times a day with highest dose of 6 tablets a day). A toxic dose is 10g or 200mg/kg (whichever is greater). The majority of patients who overdose take less than 30 g.

Summary of Benefits of MR Paracetamol:

i. Three times daily dosing and reduction of tablet burden (compared with four times daily dosing of IR formulations);
ii. MR paracetamol may be preferred over IR paracetamol for long term use in patients with chronic pain conditions such as osteoarthritis.

Summary of Risks of MR paracetamol:

i. Unpredictable and undefined pharmacokinetic profile following an overdose with MR paracetamol.
ii. Severe consequences of overdose may be more likely to occur in patients who have ingested MR paracetamol;
    a. High potential for treating clinician to not be aware that a patient has ingested MR paracetamol

b. Unpredictable pharmacokinetic profile making monitoring and treatment difficult

iii. Current best practice guidelines do not completely address MR toxicity.

iv. Chronic supratherapeutic overdose is also thought to be not uncommon. This is likely largely due to confusion about the difference in dose between MR and IR paracetamol with the maximum dose being 6 tablets per day for the MR formulation rather than 8 tablets per day for IR. This confusion may be contributed to by the products being available adjacent to one another OTC without counselling/education provided at the point of sale.

v. Paracetamol overdose can result in liver failure requiring liver transplant and may be fatal if not treated appropriately in a timely manner.

To overcome the risk associated with overdosing of Paracetamol MR Tablet, following different regulatory actions have been taken by EMA and TGA:

A. European Medicines Agency (EMA) on recommendations of Pharmacovigilance Risk Assessment Committee (PRAC) suspended the marketing of MR paracetamol formulations in September 2017 as the **advantages of a longer-acting product did not outweigh the complications of managing an overdose of the medicine**, since the treatment procedures for immediate-release products are not appropriate for modified-release paracetamol.

In many cases, it may not be known whether an overdose of paracetamol involves immediate-release or modified release products, making it difficult to decide how the overdose should be managed.

Furthermore, the **medicines will remain suspended unless the companies that hold the marketing authorizations can provide evidence of appropriate and practical EU-wide measures to help prevent overdose with these products and adequately reduce its risks.**

B. Therapeutic Goods Administration (TGA) Australia has up-scheduled MR paracetamol from ***Schedule 2 'Pharmacy Medicine'*** to ***Schedule 3 'Pharmacist Only'*** in order to ensure appropriate patient counselling on correct dosing and the risks associated with overdose, whether intentional or accidental.

- There are well established guidelines in Australia for the management of paracetamol overdose including with MR paracetamol.
- The treatment of paracetamol overdose is dependent on a number of factors and treatment given will vary accordingly. Key parameters include dose taken and time since exposure, if known.
- The mainstay of treatment is with acetylcysteine. Whether acetylcysteine is administered depends on certain clinical parameters, including the use of the paracetamol treatment nomogram which plots the blood paracetamol concentration against time.
- Other investigations include measurement of liver function to assess for liver toxicity.

Approval status of Paracetamol extended-release tablets in different regulatory authorities is as under:

S/N	Country	Authority	Product	Approval status
1.	Australia	TGA (Therapeutic Goods Administration) PANADOL OSTEO (reformulation) paracetamol 665 mg modified release tablet blister pack (260264) | Therapeutic Goods Administration (TGA)	PANADOL OSTEO paracetamol 665mg modified release tablet of M/s GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Active (Non-prescription medicine) **(Pharmacist Only Medicine)**
2.	Australia	TGA (Therapeutic Goods Administration) PANADOL BACK & NECK LONG LASTING paracetamol 665mg modified release tablets blister pack (78493) | Therapeutic Goods Administration (TGA)	PANADOL BACK & NECK LONG LASTING paracetamol 665mg modified release tablets of M/s GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Active (Non-prescription medicine) **(Pharmacist Only Medicine)**
3.	USA	US FDA Drugs@FDA: FDA-Approved Drugs	Acetaminophen 650mg extended release tablet	Active (Human OTC drug)
4.	Canada	Health Canada Search results summary (canada.ca)	ARTHRITIS PAIN EXTENDED RELIEF tablet	Approved.

			650mg (Paracetamol extended release tablet)	
5.	Finland	The Finnish Medicines Agency (Fimea) Drug search - Fimea	Panadol Extend 665mg modified release tablets of M/s GlaxoSmithKline Consumer Healthcare APS	Marketed.
6.	Denmark	Danish Medicine Agency Search - Summary of Product Characteristics (produktresume.dk)	Panodil, Modified Release Tablets 665mg of M/s GlaxoSmithKline Consumer Healthcare APS	Marketed.

List of Countries (Other than RRAs) where Paracetamol MR Tablet has been reported to be available	
i.	New Zealand **(Pharmacist Only Medicine)**
ii.	Singapore
iii.	Hong Kong
iv.	Malaysia
v.	UAE
vi.	Lebanon
vii.	Oman
viii.	Qatar
ix.	Bahrain
x.	Jordan
xi.	Kuwait
xii.	Egypt
xiii.	Saudi Arabia

Approval Status of Paracetamol MR tablets in Pakistan:

Application for registration of Panadol Extend Tablet (containing Paracetamol 665mg in modified release form) for finished import from Australia was received dated 22.06.2012 from M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi and initially considered by the Registration Board in its 243rd meeting held on 08th – 09th May, 2014. Later on, the firm revised the application from 'finished import' to 'bulk import and local repacking'. Registration Board in its 289th meeting held on 14th – 16th May, 2019 approved registration of aforementioned product such that the tablets will be imported in bulk from M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia and will be blistered and packed along-with final quality control release of the finished pharmaceutical product at M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi. The approval was granted on following grounds:

- Evidence of approval of applied formulation by the reference regulatory authority i.e., Therapeutic Goods Administration (TGA), Australia and confirmation of free sale status in Australia as determined from submitted legalized Certificate of Pharmaceutical Product (CoPP) for bulk labeled tablets.
- On-site Investigation by a panel comprising of Dr. Saif ur Rehman Khattak (Director, CDL, DRAP, Karachi), Dr. Najam us Saqib (Additional Director, DRAP, Karachi) and Mr. Kirshan Das (Assistant Director, DRAP, Karachi) for confirmation of Authenticity / Genuineness of stability data in final container closure system performed by M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi.

Reg. No.	**Product Name & Composition**	**Registration Trail**
097070	Panadol Extend Tablet Each modified release tablet contains: Paracetamol……665mg (USP Specifications) Bulk Import & Local Repacking	**Initial Reg. Date:** 08-07-2019 **Change of Source of Bulk Tablets dated 12- 03-2021:** From M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia to M/s Glaxo Welcome, S.A. Avda. Extremadura, 3, Pol. Ind. Allendeduero, Arvanda de Duero, 09400 Burgos, Spain **Change of Local Repacking Site dated 26- 10-2021**: From M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro

Information printed on label regarding management of Overdose:	In case of overdose, immediate medical management is required by visiting nearest Emergency Medical Center, even if symptoms of overdose do not appear.

Detail of Revised Application Considered in M-323-RB:

M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro has now requested for change in registration status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name along-with **end to end local manufacturing**. The product is currently registered for bulk import (of tablets) from Glaxo Welcome Spain and local repacking along-with quality control release at M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro.

Evaluation report will be placed before the Registration Board during the meeting.

Decision of M-323:

Registration Board deferred the case for following reasons:

i. *Evaluation of application submitted for change in registration status of Panadol Extend Tablet 665mg (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro along-with end to end local manufacturing.*
ii. *The applicant shall submit detail of measures adopted by other countries (whether RRA or non-RRA) to mitigate the risk as reported by EMA.*
iii. *The applicant shall also submit detail of practicable measures which will be adopted after grant of marketing authorization to prevent the risk of toxicity associated with over-dose of above-mentioned product.*

i. Evaluation Report:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate on the basis of inspection conducted on 15-09-2020.
ii. Copy of DML (000010) of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro renewed w.e.f. 31-03-2020.
iii. Approval of "Tablet (General) Section" confirmed from Licensing Division's letter dated 27-01-2022.
iv. NOC (dated 13-01-2022) issued by M/s. GlaxoSmithKline Pakistan Limited in the light of De-Merger order of Sindh High Court.
v. Relevant undertakings & commitments.

Evaluator: Mr. Abdul Mughees Mudassir (AD to CEO)

	Name, address of Applicant / Marketing Authorization Holder	GlaxoSmithKline Consumer Healthcare, Sandoz Nagar, Petaro road, Jamshoro, Sindh, Pakistan.
	Name, address of Manufacturing site.	GlaxoSmithKline Consumer Healthcare, Sandoz Nagar, Petaro road, Jamshoro, Sindh, 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. 1636 dated 02/12/2022
	Details of fee submitted	Fee Slip Number: 231886180613, PKR 30,000/- dated 22/11/2021
	The proposed proprietary name / brand name	Panadol Extend Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified-release tablet contains: Paracetamol ….665mg

	Pharmaceutical form of applied drug	Oral (Tablet)
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	20's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Panadol Osteo Paracetamol 665 mg modified release blister pack By GSK Consumer Healthcare, Australia
	For generic drugs (me-too status)	-
	GMP status of the Finished product manufacturer	-
	Name and address of API manufacturer.	Rhodia Operations SAS (Novacyl Pharmaceutical), 8 Guang Shi Xi Road, China 214185 Wuxi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol is present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Accelerated: 40°C ± 2°C, 75%RH ± 5% Long-term: 25°C ± 2°C, 60%RH ± 5% Batches: 20040226G01, 20040228G01 and 20040229G01
	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	Firm has claimed to be innovator
	Analytical method validation/verification of product	Method Verification studies have been submitted.
STABILITY STUDY DATA		
Manufacturer of API	Rhodia Operations SAS (Novacyl Pharmaceutical), 8 Guang Shi Xi Road, China	

	214185 Wuxi		
API Lot No.	Batch: DF3T : 0001265000 (Paracetamol) 0001262368 (DC-90) Batch: DFLT : 0001267970 (Paracetamol) 0001262368 (DC-90) Batch: DF3T : 0001265000 & 0001267970 (Paracetamol) 0001262368 (DC-90)		
Description of Pack (Container closure system)	Transparent PVC/PVDC 275-micron thickness/ Al foil Blister Pack		
Stability Storage Condition	Accelerated stability study: 40°C ± 2°C / 75 ± 5% RH Long-term stability study: 30°C ± 2°C / 65 ± 5% RH		
Time Period	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3 & 6 months		
Frequency	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Batch No.	DF3T	DF3L	DF3R
Batch Size	440.16 Kg	440.16 Kg	440.16 Kg
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	-
3.	Documents for the procurement of API with approval from DRAP (in case of import).	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

Panadol Extend Tablets are white to off-white, bi-layer, capsule-shaped, film-coated tablets with flat edges embossed with an 8 logo on the front face and plain on the back face.

Remarks OF Evaluator:	**Firm's Response:**
• GMP certificate of DS manufacturer and Invoice clearance from ADC.	• The applicant has submitted certificate of suitability of API by EDQM i.e., valid till to date along-with copy of invoice attested by ADC on 12-11-2019.

• Forced degradation studies of DS are required as the long-term stability has been performed on 25°C ± 2°C, 60%RH ± 5%.	• Not submitted yet

ii. Measures Adopted by other Countries (whether RRA or non-RRA) to mitigate the risk as reported by EMA:

The applicant has shared following information under the heading of "Risk Mitigation Measure Adopted in Finland":

Risk Minimization Measure	Purpose	Information
Implementing additional warnings on the packaging material/leaflet	Proposal by GSK: Inform and increase focus on use of paracetamol, increase focus on handling overdose. FIMEAS response: *Please provide the updated PI for assessment.* GSK CH response: *Updated SPC sections 4.4 and 4.9 is attached to this response.*	GSK CH commits to submit the next global data sheet v 7 after closure of the current ongoing GDS updates. The updated text linked to OD in v7: "the lowest dose necessary to achieve efficacy- should be used for the shortest duration of treatment." The updated sections in the FI SPC were approved by Fimea.
Education of HCPS	Proposal by GSK: Encourage HCPs to educate patients of safe use and storage of the medicine. Encourage HCPs to prescribe 48 tablet blister packs for acute cases, 96 tablets blister packs for chronic cases and 100 tablet bottles only for hospital use and dose dispensing. FIMEAS response: *Encouraging HCPS to educate patients on safe use and storage of the medicine and to prescribe 48 blister packs for acute case is not consider necessary.* *The 100 tablet bottles should be restricted to hospital use only. Only the blister packages should be available for dispensing to patients from pharmacies. The Applicant is asked to comment on this proposal.* GSK CH response: *We confirm that 100 tablet bottles will be restricted to hospital use only and that only*	GSK CH commits to send out communication to HCPs upon relaunch if the suspension would be lifted. The final Finnish DHCP communication that was accepted by Fimea was sent out to HCPs in FEB 2019.

	blister packages will be dispensed by pharmacies. We will make the necessary changes to implement this and in the meantime we will not produce or deliver any bottles. <u>Proposal by GSK:</u> Increased focus on risk of overdose. <u>*FIMEAS response:*</u> *Informing emergency department and the PIC that MR paracetamol is back on the market is essential as well as a reminder of the updated treatment guideline. The current Finnish guideline states that the nomogram should only guide treatment in case of acute intoxications and is not reliable in case of intoxication with MR products. To minimise the risk of liver damage the Applicant should send out a DHCP communication to the Finnish emergency departments and the PIC emphasizing this update of the guideline as well as the need for repeated sampling of paracetamol.*	
Patient information campaigns	<u>Proposal by GSK:</u> Inform about risk of liver damage and importance of appropriate use of paracetamol. Inform and increase focus on the importance of storing medicines safely – both at home and on the move. Help parent to have "safe medicine" conversations with their children.	GSK CH commits to roll out: "Safe storage of medicine" campaign. Guide to guidegivers regarding medication management in elderly. Parent's guide. Patient folder. Information campaign targeting young people.
Child proof packaging	<u>Proposal by GSK:</u> Limit accessibility for children with child resistant packages. <u>*FIMEAS response:*</u> *Will GSK implement child resistant blister packaging? And if so, the Applicant is asked to give an estimate of the timetable for this implementation.*	GSK CH is committed to implementing child resistant packaging on all their products. CRSF foil is implemented for all the registered pack types.

Furthermore, the applicant has also shared a review article on ***"Updated guidelines for the management of paracetamol poisoning in Australia and New Zealand"*** (https://pubmed.ncbi.nlm.nih.gov/31786822/)

iii. <u>Measures to prevent the risk of overdosing after grant of marketing authorization:</u>

<u>PANADOL EXTEND TABLETS - OVERDOSING PREVENTION</u>

Following are the practicable measures which will be adopted to prevent the overdosing risk of paracetamol through our product:

Globally we are mitigating the risk of overdose associated with all paracetamols' containing products including modified-release paracetamol through routine risk minimisation measures that includes product's labelling (GDS), the company's signal management activities and a targeted follow-up questionnaire (TFUQ) for medically confirmed spontaneous reports of liver or hepatobiliary adverse events in the context of paracetamol overdose. Also, our routine pharmacovigilance practices include:

- Established processes for the collection and as required, notification of any adverse events occurring anywhere in the world.
- Established processes for the regular and systematic review of ongoing safety data relating to its pharmaceutical products.

This employs a routine, pro-active process for identifying safety signals with four main components:

A. Ongoing awareness and review of important individual cases, including all reports with a fatal outcome.
B. Systematic, regular and proactive review of aggregate safety data. This includes trend analysis to detect increased frequency of reporting and, qualitative and quantitative methodologies to detect safety signals.
C. Systematic, regular review of the literature.
D. Starting 22 Feb 2018, regular review of data from EudraVigilance, the pharmacovigilance database of the EMA, for products included in EMA's list of medicines under additional monitoring as of 25 Oct 2017. Note that paracetamol is not included in EMA's list of medicines under additional monitoring.

Also, the TFUQ includes a comprehensive set of questions aimed at capturing specific and pertinent details regarding the potential paracetamol overdose such as: patient demographics, whether the patient was hospitalised, the quantity of paracetamol taken, the type of packaging, details about any other drugs ingested and quantities, whether treatment with N-acetylcysteine was given, details of any relevant laboratory results including serum paracetamol levels, N-acetyl-p-benzoquinoneimine and glutathione levels etc. Potential safety issues identified from non-clinical studies, clinical trials, individual case reviews, signal detection and data mining activities, Periodic Benefit Risk Evaluation Report/Periodic Safety Update Reports, from regulatory queries or other sources are carefully evaluated. Adverse drug reactions identified during these reviews are incorporated into the Core Safety Information for paracetamol and subsequently reflected in local country labelling.

On the basis of above locally we have following in place and in process:

1. Updated Patient information leaflet with paracetamol overdosing.
2. We have safety contact, and one may reach out to us through published e-mail and telephone numbers on our product's labelling and packaging.
3. We will establish website and upload right dosing and overdosing information for both healthcare professionals (HCPs) and patients.
4. Our on-ground expert team will reach out hospitals and provide related literature, educate on right dosing and overdosing.
5. In UK we have a website for patient awareness on different products www.letstreatitright.com we will develop one such for Pakistan and see the utility for HCPs and Patients.

In addition to above-mentioned information, the firm has also shared the following statistics regarding overdose instances reported globally with respect to paracetamol containing product:

Data Collected Globally Regarding Overdose Instances of Paracetamol Containing Products:

a. Since, Panadol Extend Tablet was launched, no complaints have been received with respect to formulation safety and no healthcare professional has raised any concern; in fact, this is currently the most in-demand product due to its efficacious nature and ease of administration.
b. Due to proper product labelling w.r.t. its indication, dosage and maximum daily intake quantity, no cases of overdosing or misuse of the product have been reported and nothing was communicated by authorities either.
c. From July 1, 2020, to December 31, 2022, a total of 46 overdose instances of Paracetamol products were reported globally as mentioned below in the country-wise table. Out of these, 20 were paracetamol combination products and junior, or children's, range products of paracetamol. Two of the remaining 26 cases are of Panadol Osteo, which is an SR formulation, while the rest are reported from the source countries as adult Paracetamol overdose cases.

Country	Count of Case Number
Australia	14
Sweden	6
Turkey	5
Spain	3
Denmark	2
Peru	2
United Kingdom	2
Canada	1
Russian Federation	1

Finland	1
China	1
South Africa	1
Colombia	1
Sri Lanka	1
New Zealand	1
France	1
Costa Rica	1
Hong Kong	1
India	1
Grand Total	**46**

d. Further dissecting the provided data with the available information of below 26 cases, global overdose instances were less than 26 during the last 30 months, as it includes some reported countries where Paracetamol SR formulation is not on the market. Out of these, 11 are reported as serious cases, and most were reported during the peak COVID period, where healthcare professionals' (HCP) accessibility was compromised.

Country	**Count of Case Number**
Australia	7
Sweden	3
Turkey	5
Spain	1
Denmark	1
United Kingdom	1
Finland	1
China	1
South Africa	1
Colombia	1
New Zealand	1
Costa Rica	1
Hong Kong	1
India	1
Grand Total	**26**

e. As a result, the proposal to educate HCPs and patients via different modes, highlighting the maximum daily intake, warnings and precautions of this formulation are helpful in ensuring its safe use in the local market.

Proceedings of M-326th Meeting:

i. Mr. Abdul Mateen, Deputy Director (Division of Pharmacy Services, DRAP) apprised the Board that the firm has merely reported number of overdose instances regardless of submitting complete case reports. Furthermore, keeping in view the practices adopted by different RRAs/ Non- RRAs, following proposals were also placed for consideration of Registration Board:

a. Possibility for change in prescription status of Panadol Extend Tablet in Pakistan from OTC to prescription only medicine; Or to be sold through pharmacies only across Pakistan *"Pharmacist only"*.
   - Or the firm should be asked about the legal status (OTC, prescription or pharmacist only) in all countries where the drug is registered/marketed.

b. Warning on outer carton/pack regarding the risk
   - Reference: Public assessment report of EMA (Page 24)

   https://www.ema.europa.eu/en/documents/referral/paracetamol-article-31-referral-prac-assessment-report_en.pdf

c. Reduction in pack size of OTC product or the firm should be asked to submit detail of pack size in all the countries where the drug is registered/marketed both for prescription and OTC product.
   - 12 caplets in Malaysia and EMA public assessment report (https://www.panadol.com/en-my/adult-products/panadol-extend/
   - Australia has decided to reduce the OTC pack size to 16 from 20 (https://www.tga.gov.au/resources/publication/scheduling-decisions-interim/interim-decision-paracetamol-access-controls-poisons-standard-questions-and-answers)

- 18 in Singapore (https://www.panadol.com/en-sg/products/adult/muscle-and-joint-pain-relief/panadol-extend.html)
- 18 in Egypt (https://www.panadol.com/en-eg/products/adult-products/panadol-joint.html)

d. Educational tool for healthcare professionals and patients for reduction of risk of overdose toxicity.

ii. Dr. Ayesha Yaqoob, Govt. Analyst, DTL, Rawalpindi apprise that Board that DTL, Rawalpindi receive some samples from the market, which show different manufacturing sites / MA Holder. Accordingly, the case was taken up by the PQCB regarding availability of 3/three different types of packs of Panadol Extend Tablet in the market.

Decision: Registration Board deferred the case on following grounds:

i. The applicant shall submit following information/ documents for further deliberation by the Board:

a. Stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of requisite information/ documents as already decided by the Registration Board in its 290th meeting under *"Requirement of The Storage Conditions for The API Stability and FPP Stability".*

b. Reports of Pharmaceutical Equivalence and Comparative Dissolution Profile Study performed against the innovator's product.

c. Justification for adopting USP specifications with reference to following claim of innovator's product regarding release profile:

USP Dissolution Test 1		**Claim of Innovator's Product (regarding release profile)**
Time	**Amount Dissolved**	**MR paracetamol tablets are constructed in <u>two layers</u>, an IR layer that is absorbed rapidly (similar to standard paracetamol formulations) and a sustained release layer which allows for the gradually release of paracetamol from tablet <u>over a period of 8 hours.</u>**
15min	**45%-65%**	
1h	**60%-85%**	
3h	**NLT 85%**	

ii. Existing registration holder i.e., M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi (DML No.000233) shall submit NOC (issued within 6 months) for grant of same brand name in favour of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro (DML No.000010) along-with a request for withdrawal/ cancellation of registration of Panadol Extend Tablet (R#097070).

iii. The firm shall submit the details of its pharmacovigilance system in line with guidelines issued by DRAP regarding the reporting of any ADR/ADE. The firm shall report any ADR/ADE accordingly.

iv. Educational tool to be adopted for healthcare professionals and patients to reduce the risk of toxicity associated with overdose

v. All the provincial health departments shall be requested to report any case/incidence regarding the Panadol Extend Tablet to the Quality Assurance Division DRAP.

<u>Post Registration-I Section</u>

1. Change in status of Product Registration Holder from Drug Manufacturing License (000234) to Drug Sale License without change in manufacturing site.

The subject mentioned application of M/s Bayer Pakistan Limited, Lahore was considered in 323rd meeting of RB for following products:

Sr. No.	**Reg. No**	**Name of Product**
1.	107229	Canesten 1, Vaginal Cream with Applicator
2.	107224	Canesten 1 Vaginal Tablet of 0.5g
3.	107225	Canesten 6 Vaginal Tablets of 0.1g
4.	107227	Canesten Clotrimazole Cream
5.	107226	Canesten Extra Bifonazole Cream
6.	111897	Baycuten N Cream
7.	109734	Baydal Tablets

The details of the sites are as under:

DMl Site	DSL Site	Manufacturing Site
DML No. 000243 Bayer Pakistan Pvt Ltd Plot No. 108, Quaid-e-Azam Industrial Esate, Kot Lakhpat, Lahore Pakistan	DSL No. 01. Bayer Pakistan Pvt Ltd. Plot No. 23 Sector No. 22, Korangi Industrial Area, Karachi 74900, Pakistan	Manufacturing site shall remain same i.e M/s Novartis pharma, C-21, S.I.T.E Karachi

Registration Board decided as follows:

"Registration Board deferred the case for opinion of Legal Affairs Division whether clause (c) of Rule 20A of Drugs (Licensing, Registration and Advertising) Rules, 1976 is also applicable for already registered drug products of such firm in Pakistan on its DML and now firm has requested for registration on DSL basis."

Accordingly, the case was referred to Legal Affairs Division and they furnished the following opinion:

"This Division is of considered view that these drug products are registered in the name of M/s Bayer Pakistan for local manufacturing as a licensee of DRAP. The validity of registered products for local manufacturing is, inter alia, dependent on validity and ownership of drug manufacturing license. As soon as the drug manufacturing license is transferred to another entity, the earlier licensee would not be able to hold registration of products. It is clear that a foreign pharmaceutical company (like Bayer) having drug sale license may enter into contract manufacturing of its research, innovator, originator drug products or drug products already registered for sale by any reference regulatory authority under rule 20A(1)(c) of the 1976 rules. In such a case the company (DSL holder) has to apply for registration of products a fresh for entering into contract manufacturing with any DML holder."

The said opinion has already been communicated to the firm for compliance. Submitted for information and consideration of Board please.

Decision: The Registration Board, in light of opinion of Legal Affairs Division (as already communicated to them) advised M/s Bayer Pakistan Limited, Lahore (DSL holder) to apply for registration of imported products a fresh for entering into contract manufacturing with any DML holder as per the contract manufacturing prescribed under the rule 20(A) of Drugs (Licensing, Registering and Advertising) Rules, 1976 amended through SRO 1347(1) 2021 dated 15th October, 2021.

Division of Quality Assurance & Laboratory Testing

RELAXATION IN LABELING AND PACKING REQUIREMENYTS FOR AMPOULES HAVING CAPACITY OF 2ML OR LESS UNDER DRUGS (LABELLING AND PACKING) RULES 1986.

This is with reference to the request of M/s Friends Glass Pvt Ltd Swabi regarding difficulties in printing of art work on glass ampoules having capacity of 1ml and printing material is so huge that it is not visible with naked eyes and it is more difficult when it comes to printing the same matter on the ampoules.

2. It is submitted that the Rule 3 of The Drugs (Labelling and Packing) Rules, 1986 that deals with labelling requirements is as under: -

(3) Manner of Labelling:

The following particulars shall appear either in print or in writing in indelible ink in a conspicuous manner on a label of the innermost container of drug and also on the in which such container is packed namely: -

(a) The registered name of the drug;

(b) If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;

(c) The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight.

Added by SRC 1122 (i) 86 dated 23-12-1986 Manual of Drug Laws or measures in metric system, or the number of units of activity as the cause may be, expressed: - (i) In the case of oral liquid preparations in terms of contents per specified volume, the volume being indicated in militaries; (ii) In the case of liquid parenteral preparations ready for administration in terms of militaries or percentage by volume or dose. Provided that in the case of a preparation contained in ampoule, it shall be sufficient if the ingredients are shown on the label or wrapper affixed to any

package in which such ampoule is issued for sale. (iii) In the case of drugs in solid form intended for parenteral administration in terms of weight or unit per milligram or gram or per container. (iv) In the case of tablets, capsules pill or other units as the case may be; and (v) In the case of other preparations in terms of percentage by weight or volume or unit-age per gram or milliliter as the case may be;

(d) The name and principal place of business of the manufacturer

(e) The drug manufacturing license number.

(f) The drug registration number.

(g) The date of expiry.

(h) Urdu version of the following namely;

(i) Name of drug (ii) dosage; and (iii) Instructions;

(i) The distinctive batch number date of manufacture and the maximum retail price;

Provided that in the case of a drug packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than two milliliter or in an ampoule containing a sterile suture or ligature and such strip foil blister or ampoule is placed in other package and also in the case of printed collapsible tubes it shall be sufficient to give the information on the outer packing containing such strips, foils, blister or ampoule.

Provided further that the registration board may allow relaxation of any of these conditions.

3. It is submitted that drug contained in an ampoule having capacity of not more than 2ml have space constrains to print all the information on the ampoule, furthermore, as per Rule 3 of The Drugs (Labelling and Packing) Rules, 1986 the Registration Board is empowered to allow relaxation of any of labelling and packing conditions.

4. In light of above it is proposed that we may allow the ampoules of capacity of 2ml or less to contain following minimum information: -

i. The registered name of the drug;
ii. If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;
iii. The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight.
iv. The name of the manufacturer
v. The drug manufacturing license number.
vi. The drug registration number.
vii. The date of expiry.
viii. Urdu version of the following namely; (i) Name of drug
ix. The distinctive batch number and the maximum retail price;

Proceedings and Decision of 326th Meeting of Registration Board.

The Board after considering the facts of the case and after thorough deliberations and technical discussion keeping in view of small size of the ampoule which is difficult to print and read, in light of provision of Section 3 of Drugs (Labelling and Packing) Rules 1986 decided following minimum particulars shall appear in print or in writing in indelible ink in a conspicuous manner on the ampoules of capacity of 2ml or less: -

i. Registered name of drug both in Urdu and English version.
ii. International non-proprietary name or Pharmacopoeial name or generic name as the case may be.
iii. DML number.
iv. Registration Number.
v. Expiry Date.
vi. Batch No.
vii. Company Name with District of its Location. (Complete address such as street No., plot etc may be relaxed e. g X (Company), plot No. Y Street Z, ABC Industrial area, Islamabad may be written as X, Islamabad)

However, on the outer packing all the information as required under Drugs (Labelling & Packing) Rules 1986 must appear in print or in writing in indelible ink in a conspicuous manner.

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